



Evaluability Assessment and Evaluation Design Phase Report

**COVAX Facility and AMC Evaluability,
Evaluation Design and Formative
Review/Baseline Study**

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List of acronyms

ACT	Access to COVID-19 Tools
ACT-A	Access to COVID-19 Tools Accelerator
AFC	Audit and Finance Committee
Africa CDC	Africa Centres for Disease Control and Prevention
AMC92	Advanced Market Commitment 92
APA	Advance Purchase Agreement
ART	Antiretroviral Therapy
AVAT	African Vaccine Acquisition Trust
BID	Better Immunization Data
BMGF	Bill & Melinda Gates Foundation
C&L	Communications and Learning
C4D	Communication for Development
CCM	COVAX Coordination Meeting
CEPI	Coalition for Epidemic Preparedness Innovations
CRD	Country Readiness and Delivery
CSO	Civil Society Organization
C-TAP	COVID-19 Technology Access Pool
DCVMN	Developing Countries Vaccine Manufacturers Network
EA	Evaluability Assessment
EAC	Evaluation Advisory Committee
EAQ	Evaluability Assessment Question
eJRF	Electronic Joint Reporting Form
ELU	Evaluation and Learning Unit
EQ	Evaluation Question
ESC	Evaluation Steering Committee
ESRC	Economic and Social Research Council
FCDO	Foreign, Commonwealth and Development Office
GDPR	General Data Protection Regulation
GFF	Global Financing Facility
HCS	Hierarchical Card Sorting
HIC	High-Income Country
HSRC	Health Systems and Response Connector
ICAI	Independent Commission for Aid Impact
IDA	International Development Association
IFAD	International Fund for Agricultural Development

IFI	International Financial Institution
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations
IPG	Independent Product Group
IRC	International Rescue Committee
KII	Key Informant Interview
LIC	Low-income Country
LMIC	Low- and Middle-Income Country
LSHTM	London School of Hygiene & Tropical Medicine
M&E	Monitoring and Evaluation
MEL	Monitoring, Evaluation and Learning
MIC	Middle-Income Country
MMGH	MM Global Health
MOPAN	Multilateral Organisation Performance Assessment Network
MSDC	Market-Sensitive Decisions Committee
MSE	Multi-Stage Evaluation
NGO	Non-Governmental Organization
NITAG	National Immunization Technical Advisory Group
NORAD	Norwegian Agency for Development Cooperation
NVDP	National Vaccine Deployment Plan
ODA	Official Development Assistance
OECD DAC	Organisation for Economic Co-operation and Development's Development Assistance Committee
PAHO	Pan American Health Organization
PEA	Political Economy Analysis
PHEIC	Public Health Emergency of International Concern
PPC	Program and Policy Committee
PPE	Personal Protective Equipment
PRG	Procurement Reference Group
Q&A	Questions and Answers
QA	Quality Assurance
QCA	Qualitative Comparative Analysis
RACI	Responsible, Accountable, Consulted, Informed
RAG	Regulatory Advisory Group
RDMIC	Research and Development and Manufacturing Investment Committee
RfP	Request for Proposals
SAGE	Strategic Advisory Group of Experts

SFP	Self-Financing Participant
SII	Serum Institute of India
SPRP	Strategic Preparedness and Response Plan
TA	Technical Assistance
TAG	Technical Advisory Group
TBE	Theory-Based Evaluation
ToC	Theory of Change
ToR	Terms of Reference
TRG	Technical Review Group
UMIC	Upper-Middle-Income Country
UN	United Nations
UNEG	United Nations Evaluation Group
UNICEF	United Nations Children’s Fund
USAID	The United States Agency for International Development
WAP	Weighted Average Price
WHO	World Health Organization
WSC	Workstream Conveners
WTO	World Trade Organization

Executive summary

As a co-lead for COVAX, the vaccines pillar of the Access to COVID-19 Tools Accelerator (ACT-A),¹ Gavi coordinates the COVAX Facility (a global risk-sharing mechanism for pooled procurement and equitable distribution of COVID-19 vaccines) and administers the COVAX Advanced Market Commitment (AMC; an innovative financing mechanism to frontload Official Development Assistance (ODA) and donations for vaccines among 92 middle- and lower-income countries that cannot fully afford to pay for COVID-19 vaccines themselves, and to ensure fair and equitable access).²

In response to the Gavi Board's request for the COVAX Facility and COVAX AMC to be independently and robustly evaluated, the purpose of this phase of the evaluation has been to:

- *assess the readiness for an evaluation*, including the coherence and completeness of the COVAX Facility and COVAX AMC design, the availability of data to answer the evaluation questions (EQs), and the usefulness of doing so; and
- *set out an appropriate and robust multi-stage evaluation design*, using the findings of the above, that can be utilized over the life course of the COVAX Facility and COVAX AMC.

Itad, a specialist monitoring, evaluation and learning (MEL) consultancy, was selected to complete this phase of work and, following its successful completion, conduct a formative review and baseline study.

This report has benefited from extensive feedback provided by the Gavi Evaluation and Learning Unit (ELU), the Secretariat and Office of the COVAX Facility, and a broad range of other stakeholders engaged in the operationalization of COVAX, as well as a broader set of stakeholders with an interest in COVAX.

Assessment of readiness for an evaluation

Overall, the assignment, based on a substantial review of the available literature and information systems as well as broad stakeholder engagement, finds that:

1. The COVAX Facility and COVAX AMC design is coherent and complete enough to robustly evaluate. However, its complexity (i.e. with many interacting global agents, serving a range of different functions across a number of sectors, requiring feedback from participant countries and communities to refine ideas and adjust approaches) and frequent changes to the design will pose a challenge for the evaluation.
2. There is sufficient data available to answer the majority of the EQs posed in the Request for Proposals (RfP), although these questions do not explicitly mention all of the programmatic areas of the COVAX Facility and COVAX AMC that need to be evaluated – i.e. market shaping, procurement and delivery, equitable allocation, and country readiness and delivery (CRD). Revised EQs are presented below.
3. There is substantial interest across a range of stakeholders in answering EQs that seek to understand: the appropriateness of the intervention design; how well different components of the intervention design have been implemented; and how the COVAX Facility and COVAX AMC has worked within the geopolitics and context of the COVID-19 pandemic response to achieve its overall goal of strengthened equity and fairness in the allocation and distribution of, and access to, COVID-19 vaccines.³

¹ The ACT-A was launched in April 2020 to convene governments, multilateral organizations, private sector and civil society partners to coordinate, fund, develop and equitably deploy COVID-19 tools to bring about the end of the COVID-19 pandemic. Its four technical partnerships, led by nine partners, consist of three vertical pillars (vaccines, therapeutics and diagnostics) and a health systems connector.

² Gavi. (2020, September 3). *COVAX explained*. <https://www.gavi.org/vaccineswork/covax-explained>

³ Equity and fairness are at the heart of the COVAX Facility and COVAX AMC's design and can be considered in at least three ways: in the distribution of and access to vaccines across country income categories; between individual countries; and within countries.

Multi-stage evaluation design



This section sets out the purpose, principles and strategic direction of the multi-stage evaluation, which is expected to take place over a 10-year horizon, in line with the initially envisaged life span for the COVAX Facility and COVAX AMC. We note that this could be adjusted, for instance if the COVAX Facility and COVAX AMC were to be integrated into Gavi's core business.



The following are the priority users and uses of the evaluation:

- Gavi Board, primarily to hold the Gavi Secretariat and Office of the COVAX Facility to account for their role in implementing the COVAX Facility and COVAX AMC, alongside other implementing partners, for the use of ODA and achievement of results to donors, investors and all countries participating in COVAX.
- COVAX implementing partners, particularly the Gavi Secretariat and Office of the COVAX Facility, to enable (a) rigorous testing, learning and adjustment of the complex COVAX Facility and COVAX AMC model to ensure fitness for purpose within its operating environment and optimize the conditions for desired results to be achieved; and (b) comprehensive tracking of the progress and contribution of the COVAX Facility and COVAX AMC to intended results, with explanations of how and why this is or is not being achieved.
- The global health community writ large, including AMC countries and regional stakeholders, with a proactive focus on equity, to report objectively on the extent to which COVAX has been able to address power imbalances to ensure equitable access to COVID-19 vaccines and inform future pandemic preparedness.

The proposed set of EQs is presented in Table A. These have been grouped by module to provide an organizing framework to structure the evaluation design, and in some cases have been revised to ensure that they are answerable, useful, and comprehensive of the issues at hand. The questions cover the operational and programmatic components of the COVAX Facility and COVAX AMC.

Table A - Core EQs for the multi-stage evaluation

Evaluation module	EQ #	EQs (Bold = headline EQ)
 1. Right things: Design	1	Is the design and intervention logic underpinning the COVAX Facility and AMC clear, relevant, inclusive and appropriate to enable achievement of intended outcomes and impact?
	1.1	Are the overall design of the COVAX Facility and AMC and specific strategies clearly justified and documented, and is the overall design clear and coherent?
	1.2	Recognizing the dynamic nature of the pandemic and geopolitical context, what design revisions were made since the original design, and why?
	1.3	How did external stakeholders and COVAX partners contribute to the original design, and subsequent design revisions of the COVAX Facility and AMC, and what impact did this have?
	1.4	Are any design revisions needed for course correction? What are the design lessons for future pandemic responses?
 2. Right way: Implementation	2	Have the COVAX Facility and AMC been successfully implemented?
	2.1	Have the COVAX Facility and AMC been operationalized successfully? (operational domain)
	2.1.1	Have the COVAX Facility and AMC management structures/governance arrangements been fit for purpose?
	2.1.2	Have the COVAX Facility and AMC risk management processes been fit for purpose?
	2.1.3	To what extent were the estimated costs of setting up and implementing the COVAX Facility and COVAX AMC in terms of finances and staff allocation reasonable and appropriate?
	2.1.4	Has the level of stakeholder engagement and communication been appropriate?
	2.2	To what extent have the specific COVAX Facility and AMC programmatic/intervention areas been implemented successfully? (programmatic domain)
	2.2.1	To what extent has an appropriate resource mobilization strategy been established and implemented to secure adequate resources for full and timely implementation of intended activities?
	2.2.2	To what extent have market shaping activities been implemented to ensure that COVID-19 vaccines are accessible and affordable for lower-income countries?
	2.2.3	To what extent have the COVAX Facility and AMC supported procurement and delivery functions to ensure that COVID-19 vaccines are provided to participants as planned?
	2.2.4	To what extent have the COVAX Facility and AMC supported the operationalization of the allocation mechanism to ensure a fair and equitable distribution of COVID-19 vaccines?
2.2.5	To what extent have the COVAX Facility and AMC supported CRD to facilitate the rollout of COVID-19 vaccines at the scale required to achieve intended outcomes and impact?	

 <p>3. Right results: Outcomes and impact</p>	3	To what extent have the COVAX Facility and AMC, alongside the roles of other COVAX implementing partners, contributed to the achievement of intended outcomes and impact within the geopolitical and economic landscape?
	3.1	To what extent have the COVAX Facility and AMC intended intermediate outcomes been achieved?
	3.2	To what extent have the overall COVAX Facility and AMC intended outcomes and goals been achieved?
	3.3	What is the evidence to suggest that the COVAX Facility and AMC incurred unintended consequences and results beyond the ToC, and what were the implications?
	3.4	How have the COVAX Facility and AMC, alongside the roles of other COVAX implementing partners, contributed to achievement of outcomes and impacts within the global geopolitical and economic landscape?
	3.5	What are the most important barriers and enablers to achieving the outcomes and goals in the COVAX ToC at all levels of implementation?
 <p>4. Learning</p>	4	What lessons can be drawn from the design and implementation of the COVAX Facility and COVAX AMC for course correction, Gavi 5.0, and future pandemic responses?
	4.1	What are the most important lessons learned through design and implementation experience that have implications for COVAX Facility and AMC course correction?
	4.2	What are the most important lessons learned through design and implementation experience that have implications for Gavi 5.0?
	4.3	What are the most important lessons learned through design and implementation experience that have implications for future pandemic responses?
	4.4	What can be learned from other agencies/arrangements/contexts and applied to the COVAX Facility and/or COVAX AMC for the achievement of outcomes and impact?
	4.5	What can be learned from a comparison of countries' experiences of securing maximum possible vaccination supply, and applied to the COVAX Facility and/or COVAX AMC for the achievement of outcomes and impact?

In terms of the scope of work, while the evaluation is focused on Gavi and the COVAX Facility and COVAX AMC, it is unlikely to be possible or most helpful to evaluate these in isolation. Rather, the evaluation should consider the interconnectedness of roles, responsibilities and ways of working between agencies to facilitate COVAX Facility and COVAX AMC results. The evaluation should also consider the COVAX Facility and COVAX AMC in the context of COVAX and ACT-A more generally and the geopolitical and wider contextual factors at play. As such, this will necessarily involve taking into consideration factors both within and outside of Gavi's direct control, and factors over which Gavi has both higher and lower levels of control and for which it can be held accountable.

The evaluation design should be responsive to a number of considerations and design features:

- To meet stakeholder needs, the evaluation approach should blend the principles of (i) a periodic and phased formative-summative evaluation and (ii) real-time evaluation. This will enable evaluation of specific components of the COVAX Facility and COVAX AMC Theory of Change (ToC), as well as providing a coherent evaluation narrative on its overall contribution to outcomes and impact. It will involve:
 - periodic baseline, midterm and end-term evaluation exercises covering the full scope of work over the 10-year horizon, including stage-specific questions of relevance to each phase;
 - the flexibility to conduct 'rapid reviews' focused on specific parts of the ToC where learning is needed quickly, such as to meet policy or programmatic needs and/or provide evidence on emerging risks;
 - collaboration with the Gavi ELU and COVAX Facility and COVAX AMC MEL systems which would be responsible for a continuous real-time learning function; and
 - all evaluation activity being conducted in a coordinated and participatory manner, with a heavy emphasis on utilization and learning.
- The complicated nature of the COVAX Facility and COVAX AMC design and the context it is operating in requires a complexity-aware design. Further, the types of EQs, the demand for findings at different times for different uses, the range of methods within the design, and the scale of the evaluation mean that a mixed-method design is appropriate and make it necessary to construct the evaluation from a suite of purpose-specific modules: right things; right way; right results; and learning.
- There is a clear case for the primary evaluation approach to be theory-based. This will require a well-defined ToC that captures the mechanisms and contexts that explain how the intended outcomes will be achieved, and against which the design, implementation and results can be evaluated. We

recognize that the COVAX Facility and COVAX AMC design and the context in which it is operating are highly dynamic. As such, and to ensure that the evaluation findings are as current and relevant as practicable, the ToC will require frequent revision and updating throughout the evaluation process.

4. To assess COVAX Facility and COVAX AMC results, the evaluation should adopt a generative causation approach – i.e. one that works with a theory-based approach to examine the extent to which, how and why an intervention has produced or influenced observed results.
5. Within the family of generative causation, theory-based evaluation approaches, either contribution analysis or realist evaluation could be used to good effect to answer the EQs. However, contribution analysis will be the most practical and useful to implement, primarily due to the lower requirement for stakeholders (who have very limited time) to engage with the evaluation.

Figure A presents the evaluation’s envisaged areas of focus and how these will evolve over time and at different phases of the evaluation. This includes:

- **Phases:** As shown in orange, the 10-year evaluation life span is split into three phases covering the need for periodic baseline, midterm and end-term evaluation exercises. Rapid reviews would be conducted flexibly across those phases, alongside continuous learning led by the Gavi ELU.
- **Modules:** The four modules and high-level questions for each are presented in green on the left-hand side, with the green arrows running from left to right indicating the relative emphasis placed on each across the evaluation phases.
- **Programmatic areas:** The five programmatic areas identified in the ToC are presented in blue. Each of the areas will be considered at each phase but at different levels of intensity, as indicated by the diagonal arrows. This is dictated by the information that is available and what is most useful to be answered at a given moment in time.

Figure A - Multi-stage evaluation plan

		COVAX Facility and AMC external, formative-summative evaluation phases		
		Phase 1 (2022–2023): Formative review and baseline assessment	Phase 2 (2024–2027): Periodic summative midterm evaluations	Phase 3 (2028–2030): Summative end-term evaluation
		Rapid evaluations in areas of particular interest/need		
Evaluation modules	Right things: Is the design and intervention logic underpinning the COVAX Facility and COVAX AMC clear, relevant, and appropriate?	Predominant focus during the formative review and baseline study		
	Right way: Have the COVAX Facility and COVAX AMC been successfully implemented?	Continued focus throughout formative-summative evaluation phases		
	Right results: To what extent have the COVAX Facility and AMC contributed to the achievement of intended outcomes and impact?	Increasing focus throughout formative-summative evaluation phases		
	Learning: What lessons can be drawn on the design and implementation of the COVAX Facility and COVAX AMC?	Continued focus throughout formative-summative evaluation phases		
		Strong focus in formative review and baseline study, as well as midterm	Continued focus throughout evaluation phases	Increasing focus throughout evaluation phases
		Resource mobilization	Market shaping Equitable allocation	Procurement and delivery Country readiness
		Cross-cutting programmatic areas		

* Subject to change and/or refinement based on the trajectory of COVAX Facility and longevity of COVAX AMC

Table B presents a summary of the perceived risks, challenges and limitations to operationalizing the multi-stage evaluation, alongside proposed mitigating measures and recommendations to take forward.

Table B - Risks, challenges and limitations

Risk, challenge, limitation	Mitigating measure(s)
<p>The evaluation scope of work does not meet all stakeholder needs, particularly with respect to the global health community's desire for holistic reporting on the extent to which COVAX has been able to (i) address power imbalances to ensure equitable access to COVID-19 vaccines and (ii) support efforts that inform future pandemic preparedness efforts.</p>	<p>Significant efforts have been made during the evaluability assessment phase to elicit a broad range of views on the evaluation purpose and scope, which have informed the proposed evaluation design and the communications and learning plan. The proposal for holistic formative-summative evaluation processes, interspersed with rapid reviews in select areas to inform learning, and continuous learning led by the ELU is designed to best meet needs.</p> <p>With respect to the specific request referenced, fully answering this question would require a broader remit than this evaluation's focus on just the COVAX Facility and COVAX AMC. We propose to mitigate this risk to the extent possible through this evaluation with methods such as political economy analysis, to explore how power imbalances and political and economic concerns and incentives have influenced design and implementation decisions in the COVAX Facility and COVAX AMC, and country decision-making processes on whether and how to engage with the COVAX Facility and COVAX AMC.</p> <p>It is, however, recommended that Gavi work with other COVAX implementing partners to integrate/align this evaluation process with others conducted on similar topics and other areas of COVAX to learn lessons more holistically.</p>
<p>Fatigue within the Office of the COVAX Facility and other COVAX implementing partners, and limited bandwidth to engage with the evaluation, may reduce ability to obtain all of the most relevant data sources and solicit sufficient evidence to robustly answer EQs.</p>	<p>While country stakeholders and the staff of COVAX implementing partners are extremely busy and will have limited time to engage with the evaluation, the evaluability assessment process did indicate strong interest and willingness to do so. Nonetheless, a number of steps are included within the proposed approach to mitigate this risk:</p> <ul style="list-style-type: none"> • The proposed evaluation design and methods are made in part based on the availability of stakeholders to engage in the evaluation process. • The expectations for stakeholder engagement for each evaluation exercise are clearly presented in this report, alongside the implications of this not being met. • Efforts will be made to reduce the evaluation footprint, such as by minimizing the number of requests of each stakeholder, holding focus group discussions where feasible, making use of web-surveys and remote working (including for interviews and learning events) where possible. • Agreement on the timing of each evaluation exercise will be based, in part, on stakeholder availability. • Sufficient time to collect data will be built into the workplan for each evaluation exercise, designed to give greater flexibility to stakeholders on when to provide their inputs.
<p>Limited involvement of broader stakeholder groups (i.e. beyond the core partners directly engaged in implementing COVAX) in data collection may affect perceived or actual objectivity and independence of evaluation findings.</p>	<p>Ensure engagement with a broad set of stakeholder groups/constituencies representing the key bodies and working structures involved in the governance, management and implementation of COVAX, and specifically the COVAX Facility and COVAX AMC. Of particular importance is the need to engage with a broad range of representatives from the Global South, and specifically Advanced Market Commitment 92 (AMC92) country representatives and civil society representatives, as well as key partners (e.g. the African Vaccine Acquisition Trust (AVAT), the Pan American Health Organization (PAHO), the United Nations Children's Fund (UNICEF) and the World Health Organization (WHO)).</p> <p>Steps are also proposed to ensure that the evaluation has good governance and oversight itself, including with:</p> <ul style="list-style-type: none"> • An owner within Gavi, anticipated to continue to be from the ELU, working in strong collaboration with the Office of the COVAX Facility. • A steering and technical advisory group internal to the evaluation team to guide the evaluation and to act as a broker, as needed, with external stakeholders. • An evaluation team with strong internal capacity to implement the evaluation, a robust methodology and workplan in place, access to required data, and strong quality assurance function, led by a senior evaluation expert, to ensure that the evaluation is implemented as intended and in adherence to best practice and ethical guidelines. • An advisory panel to the Gavi Secretariat to advise on quality, fitness for purpose, and risk. We note that the Evaluation Steering Committee and Evaluation Advisory Committee jointly meet this need.
<p>Different perspectives and understandings of the intervention logic may make it difficult to develop a single ToC that is</p>	<p>Our approach to evolving the ToC has involved: (a) eliciting various stakeholders' existing conceptions of how the COVAX Facility and COVAX AMC is expected to work; and (b) constructing a single model that is evaluable but seeks to represent the diversity of stakeholder perceptions elicited. We have not yet conducted the planned participatory exercise to systematically explore and build consensus around the ToC for the evaluation. This</p>

<p>universally accepted, thus reducing buy-in among some stakeholders.</p>	<p>workshop should take place at the outset of the proposed formative review and baseline study with this purpose in mind and to ensure that the ToC is sufficiently well developed to be evaluable. It is recommended that the Gavi ELU support the facilitation of this workshop.</p>
<p>Stakeholder views and perspectives may be influenced by the high level of commentary on COVAX in the media and academic and gray literature.</p>	<p>While we cannot guarantee that stakeholder inputs are not influenced by the media, political context and commentary surrounding COVAX, steps are proposed to mitigate the risk that the data collected by the evaluation (and subsequent findings, conclusions and recommendations) might reflect such stakeholder bias. The steps are as follows:</p> <ul style="list-style-type: none"> • Selection of a cross-section of stakeholders to be interviewed, including the broad set of stakeholder groups/constituencies involved in the governance, management and implementation of the COVAX Facility and COVAX AMC. Of particular importance is the need to engage with a broad range of representatives from the Global South, and specifically AMC92 country representatives and civil society representatives, as well as key partners (e.g. AVAT, PAHO, UNICEF and WHO). This will enable us to speak to informed experts able to assert their own independent viewpoints and different world viewpoints – cutting through the media discourse and commentary, to help us form independent and well-rounded judgments. • Ensuring the positionality of the respondent is recorded (beyond job title and organization), as this will help at analysis stage to separate out and triangulate different findings from different stakeholder groups. • Triangulation with other evidence, and how this has been established and evolved over time, and building in of flexibility to pursue emerging or unexpected lines of enquiry.
<p>The evolving nature of the pandemic and the intervention logic for the COVAX Facility and COVAX AMC may limit the applicability of EQs, findings, conclusions and recommendations.</p>	<p>Through the ToC development process we will seek to capture the evolution of the intervention logic over time. Recognizing the responsiveness of the COVAX Facility and COVAX AMC design to an evolving context, each stage of the evaluation will start with an update of any revisions of design and strategy since the last assessment. The ToC will be updated as needed. Every stage of the evaluation will include a ToC situation assessment and assess the relevance, coherence and appropriateness of design choices, including the decision-making process as well as the content of any design revisions.</p> <p>This response will be appropriate for most changes to the intervention logic. However, it may not cover all eventualities (e.g. where COVAX was ceased midterm or where the design was changed so much that prior evaluation efforts became redundant). In such a situation, the evaluation scope of work and design would need to be immediately revised.</p> <p>We have proposed periodic evaluation processes, with stage-specific questions at each juncture, interspersed with rapid reviews on specific issues of interest. We have also proposed an approach and methods that major on understanding the importance of context to implementation and results. This will allow the evaluation to ensure it is asking relevant questions and will take account of the evolving context at any given moment in time. We also note that, while the evaluand design has been highly dynamic in its first two years of operations, we could also reasonably expect it to reach more of a steady state in years to come.</p>
<p>A number of aspects of the evaluation may be highly sensitive and possibly contentious, for instance when seeking to understand the incentives, relationships, and distribution and contestation of power between stakeholders engaged in the design and operationalization of the COVAX Facility and COVAX AMC. This may result in some stakeholders seeking to discredit the evaluation findings in order to avoid addressing the issue(s).</p>	<p>We recognize the timeliness of this independent evaluation and the high stakes involved, and have set out an approach to deliver robust, evidence-based insights in response to the EQs and to meet the evaluation purpose. Conducting evaluative work can involve delivering difficult messages on things that may not be working as well as they should, or that could be done differently. We are mindful of the intensity and level of effort the COVAX implementing partners have invested in establishing the COVAX Facility and COVAX AMC and delivering results, and in response our communication will always be clear, constructive and appreciative, but we will not shy away from being critical where we feel it is needed. We will work hard to build relationships with key stakeholders to facilitate constructive exchanges, ensuring that what we say is always grounded in sufficiently robust evidence. This will include engaging with our Technical Advisory Group to ensure that messaging is tailored appropriately and, where needed, comes from the right people.</p> <p>It is further recommended that the Gavi ELU ensure that the steps proposed to ensure good governance for the evaluation are fully adopted (see above) to further reduce the risk that the evaluation findings are unfairly criticized or discredited.</p>

Some causal pathways in the ToC are not able to be fully explored and understood, due to a lack of data and evidence on the completion of non-Gavi COVAX implementing partner activities and results. This may mean that only partial responses to EQs can be provided.

The evaluation will not evaluate other COVAX implementing partners but will consider the interconnectedness of roles, responsibilities and ways of working between implementing partners to facilitate COVAX Facility and COVAX AMC results. It will do this in two ways:

- It will draw on the findings, conclusions and recommendations of other evaluation processes and evidence on the design, implementation and results of their work (i.e. CEPI's role in development and manufacturing; WHO's role in policy and allocation; and UNICEF's and PAHO's roles in procurement and delivery). This will aid an understanding of how the ToC has played out in practice.
- It will consider the 'contribution' of Gavi to areas that multiple COVAX partners jointly administer, particularly those areas that Gavi is not primarily responsible for (e.g. allocation, country readiness support, procurement and delivery).

It is recommended that the Gavi ELU maintain contact with COVAX implementing partners and other groups (e.g. the Organisation for Economic Co-operation and Development (OECD) COVID-19 Global Evaluation Coalition) to keep abreast of other evaluation processes and gain access to documents as soon as possible.

Evaluation activities for Phase 1 (2022–23)

Formative review and baseline study design – to be conducted in 2022

The design of the formative review and baseline study will broadly follow the outline of the multi-stage evaluation presented above. This will review what has worked well and less well to date in designing and operationalizing the COVAX Facility and COVAX AMC and take a snapshot of progress against the ToC at this point in time. As such, it will meet both an overall accountability and learning purpose in and of itself, as well as collecting baseline data essential for measurement of progress over time on the effectiveness and performance of the COVAX Facility and COVAX AMC.

More specifically, the scope of work for the four evaluation modules will focus on:

Right things (design): The evaluation will interrogate whether the COVAX Facility and COVAX AMC and its components were and remain relevant to the problems they were designed to address, by assessing: (1) whether the ToC/intervention design (and revisions) are appropriate and based on evidence and with clear assumptions; (2) what change in the pandemic or geopolitical context prompted design revisions; (3) whether and how stakeholders were involved in original design and subsequent revisions; (4) whether any design changes are needed for course correction; and (5) whether lessons can be learned for future pandemic responses.

Right way (implementation): A formative, learning-focused assessment of implementation progress for each of the operational and programmatic areas of the ToC:

- *Operational domain:* These EQs interrogate whether the COVAX Facility and COVAX AMC have been implemented successfully, by conducting an overall assessment of the extent to which the program has been implemented according to plans, with a specific focus on the extent to which (1) the COVAX Facility and COVAX AMC management structures and governance arrangements are fit for purpose, (2) risk management processes have been fit for purpose, (3) the costs of setting up the COVAX Facility and COVAX AMC were reasonable and appropriate, and (4) stakeholder engagement and communication has been appropriate.
- *Programmatic domain:* This is focused on understanding if resource mobilization, market shaping, procurement and delivery, equitable allocation and CRD inputs, activities and outputs have been implemented successfully and as intended.

Right results: The evaluation will seek to understand the available evidence on the achievement of outcomes and goals (intended and unintended), the contribution of the COVAX Facility and COVAX AMC to these results, and the barriers and enablers to their achievement.

Learning: Summarizing and prioritizing lessons learned, building on the work done under the earlier modules (to inform immediate course correction) and on what can be learned from other agencies, arrangements and contexts and applied for the achievement of intended outcomes and impact. This will

include opportunities for transformative learning, for instance on the overall design of the COVAX Facility and COVAX AMC and the contextual constraints which influence this design, as well as implications for future pandemic preparedness.

Having constructed an 'evaluation' ToC, the principal methods for the evaluation will be as follows:

- **Political economy analysis** will be used to identify the political and practical dimensions of designing and operationalizing a global vaccine procurement and delivery mechanism, and to analyze the appropriateness of the selected design within the context of the incentives, relationships, and distribution and contestation of power between the different stakeholders engaged and with interests in its design and operationalization.
- **Benchmarking** will be used in a variety of ways across the scope of work, including to benchmark design decisions against criteria to assess the appropriateness of decision making, and to establish if the right systems, processes and capacities were/are in place through comparison with established norms, standards, best practices and comparator organizations.
- **Process tracing** will be used to assess whether intended actions and activities have been implemented as intended, and whether the linkages and assumptions underpinning the ToC have worked as intended, and – where this is not the case – explore how and why not. This will include analysis of alternate explanations for observed results and of unintended consequences and barriers and enablers to the achievement of results.
- **Root cause analysis** will be used to analyze the underlying causes of observed issues or challenges during implementation, where the root causes are not well understood.
- **Contribution analysis** will, building on findings from other methods, be used to understand how and why the COVAX Facility and COVAX AMC has contributed to observed outcomes.

A robust approach to synthesis will enable the generation of well-rounded, evidence-based responses to high-level EQs, overall conclusions and recommendations.

Data collection will necessarily involve a broad review of the available documentation and literature, as well as information sources providing data and evidence of relevance to the evaluation. It will also involve a series of country case studies, purposively sampled, to triangulate the data collected from other sources and extend the data collected to capture country-specific experiences and contexts that will enrich the findings for a number of EQs.

It is recommended that the evaluation seek to engage with a broad set of stakeholder constituencies representing the key bodies and working structures involved in the governance, management and implementation of the COVAX Facility and COVAX AMC. Of particular importance is the need to engage with a broad range of representatives from the Global South, and specifically AMC92 country representatives and civil society representatives, as well as key partners (e.g. AVAT, PAHO, UNICEF and WHO). Such efforts will accommodate the limited time some stakeholders are able to devote to the evaluation, such as by minimizing the number of requests of each stakeholder, holding remote interviews and focus group discussions where feasible, and making use of web-surveys. Although it is possible to reduce the evaluation's access to stakeholders for interview, this will have implications for the scope, scale and quality of work.

Other evaluative activity for Phase 1 of the evaluation

Rapid reviews are proposed to support the Office of the COVAX Facility in responding to particular areas of need – i.e. to generate learning where it is needed quickly to influence course correction; generate a better understanding of the implementation context; and/or evaluate in detail the efficiency, effectiveness, sustainability or equity of COVAX Facility and COVAX AMC programmatic areas. The topics indicatively proposed related to CRD, the humanitarian buffer and/or securing supply.

Continuous learning, led by the Gavi ELU, will be supported by the evaluation team through the facilitation of dedicated ‘learning point’ meetings, sense-making and/or recommendation co-creation workshops, and updates to plans for communication, learning and dissemination for the Office of the COVAX Facility/Gavi ELU to implement.

Recommendations to operationalize Phase 1 of the evaluation

Assuming that the proposed design options are agreed and accepted, a number of recommendations are made to operationalize the evaluation approach:

- Gavi should work with other COVAX implementing partners to integrate/align this evaluation process with others to more fully answer bigger-picture questions than this evaluation (which is focused on Gavi and COVAX Facility and COVAX AMC) will be able to – for instance in relation to whether, how and why COVAX as a whole has been able to address power imbalances to ensure equitable access to COVID-19 vaccines.
- Sufficient resources should be devoted to the evaluation function to ensure that:
 - The Office of the COVAX Facility/Gavi ELU is sufficiently capacitated to implement a continuous learning function, as supported by the evaluation, and can help to ensure that methodologies and findings are well understood, as well as guiding and coordinating the formative-summative evaluation work and rapid reviews, particularly if these are conducted by different evaluators.
 - Formative-summative evaluations holistically cover what has worked well and less well in the design, set-up and implementation of the COVAX Facility and COVAX AMC, and in terms of what results have been achieved.
 - Rapid reviews can be conducted, outside of the core formative-summative evaluation work, to respond to particular areas of need.
 - A good governance function is maintained (e.g. with a well-resourced ‘owner’ of the evaluation within the Gavi Secretariat/Office of the COVAX Facility, and continued Evaluation Steering Committee and Evaluation Advisory Committee functions).
 - A strong evaluation team is selected with internal capacity to implement the evaluation, with a robust methodology and workplan in place, access to required data, and strong technical advisory support across the scope of work and quality assurance function.
- Efforts should be made by the ELU and others within the Gavi Secretariat and Office of the COVAX Facility to ensure sufficient stakeholder engagement in line with the evaluation plan developed, for instance to meet expectations for key informant interviews (KIIs), workshops, sense-making and co-creation activities.
- The Gavi ELU should maintain contact with COVAX implementing partners and other groups (e.g. the OECD COVID-19 Global Evaluation Coalition) to keep abreast of other evaluation processes and gain access to documents as soon as possible.
- Strengthen data availability on the recipients of COVID-19 vaccines, including disaggregation by vulnerable populations in participant countries, by taking steps to improve Electronic Joint Reporting Form (eJRF) reporting completeness, triangulating data from other sources, and/or undertaking special studies.

1. Introduction

As a co-lead for COVAX, the vaccines pillar of the Access to COVID-19 Tools Accelerator (ACT-A),⁴ Gavi coordinates the COVAX Facility (a global risk-sharing mechanism for pooled procurement and equitable distribution of COVID-19 vaccines) **and administers the COVAX Advanced Market Commitment (AMC;** an innovative financing mechanism to frontload Official Development Assistance (ODA) and donations for vaccines among 92 middle- and lower-income countries that cannot fully afford to pay for COVID-19 vaccines themselves, and to ensure fair and equitable access).

The COVAX Facility design was conceptualized by the Coalition for Epidemic Preparedness Innovations (CEPI), Gavi and partners (representatives from vaccine manufacturers) and with input from experts and stakeholders, including the Bill & Melinda Gates Foundation (BMGF), the United Nations Children’s Fund (UNICEF), the World Health Organization (WHO), the World Bank and developing countries, civil society and donors.⁵

Alongside Gavi, COVAX is co-led by CEPI (lead for vaccine development and manufacturing) and WHO (lead for policy and allocation), alongside key delivery partners UNICEF and the Pan American Health Organization (PAHO) in the Americas. Its overall aims are to accelerate the development and manufacture of COVID-19 vaccines and to guarantee fair and equitable access for every country.

Despite the COVAX Facility and COVAX AMC being designed to distribute and ensure access to COVID-19 vaccines based on principles of equity and fairness, the global distribution of COVID-19 vaccinations administered to date has been heavily skewed towards higher-income countries. Equity and fairness are at the heart of the COVAX Facility and COVAX AMC’s design and can be considered in at least three ways: in the distribution of and access to vaccines across country income categories (i.e. high-income countries, middle-income countries and low-income countries); in the distribution of and access to vaccines between individual countries; and in the distribution of and access to vaccines within countries, such as between geographical areas and population groups and by gender. Taking the former, while recent estimates suggest that 113 vaccine doses have been administered per 100 population globally, this figure stands at just over 14 doses per 100 population in lower-income countries.⁶ These statistics have led to COVAX receiving negative press and criticism in some well-respected journal articles. However, the full set of factors driving these headline statistics has not been fully analyzed or articulated.

The overarching objective of this phase of the evaluation is to establish a robust evidence base to support a timely and effective multi-stage evaluation of the COVAX Facility and COVAX AMC. Given emerging gaps between plans and practice, the rationale for the evaluative work laid out in the Request for Proposals (RfP) is strong. This is critical to shaping and steering the way forward through the provision of insights across the continuum of design to initial implementation, and to set the course for a robust evaluation and learning approach in the future. In line with the requirements set out in the RfP, this phase of evaluative work has been operationalized in two stages:

1. An **evaluability assessment** to assess the coherence and completeness of the COVAX Facility and COVAX AMC design (evaluability in principle), the availability of data (evaluability in practice) to answer the evaluation questions (EQs), and the usefulness of doing so.
2. Refining and preparing an appropriate and robust **multi-stage evaluation design**, directly informed by the findings and recommendations for strengthening evaluability and/or appropriate design set out in the evaluability assessment.

⁴ The ACT-A was launched in April 2020 to convene governments, multilateral organizations, private sector and civil society partners to coordinate, fund, develop and equitably deploy COVID-19 tools to bring about the end of the COVID-19 pandemic. Its four technical partnerships, led by nine partners, consist of three vertical pillars (vaccines, therapeutics and diagnostics) and a cross-cutting health systems connector.

⁵ Gavi. (2020, June 24). *Report to the Board, 05 – COVID-19 Vaccine Development, Access and Delivery*.

https://www.gavi.org/sites/default/files/board/minutes/2020/24-june/05%20-%20COVID-19_Vaccine%20Development%20Access%20and%20Delivery_Corrected.pdf

⁶ World Health Organization. (2021, November 25). *COVID-19 Dashboard, Situation by Region, Country, Territory and Area*. <https://covid19.who.int/table>. As at 24 January 2022.

This report has benefited from extensive feedback provided by the Gavi Evaluation and Learning Unit (ELU), Secretariat and Office of the COVAX Facility, and a broad range of other stakeholders engaged in the operationalization of COVAX, as well as a broader set of stakeholders with an interest in COVAX. A summary of this feedback and our response to it is provided in Annex 20.

2. Evaluability assessment

The purpose of the evaluability assessment is to systematically and robustly assess the state of readiness for an evaluation.⁷ This provides the foundation on which to design the evaluation. Given the high-profile and global importance of the COVAX Facility and COVAX AMC, we understand that the evaluability assessment is not an exercise to determine ‘if’ the COVAX Facility and COVAX AMC are ready to be evaluated but rather to pinpoint ‘how’ they can best be evaluated in the desired time frame and within a reasonable resource envelope to meet stakeholder needs. In light of this, the evaluability assessment has involved a substantial document review and broad stakeholder engagement to understand and stress-test the current COVAX Facility and COVAX AMC design/Theory of Change (ToC), assess the availability to data to answer the EQs, and highlight the weaknesses and gaps that are critical to address in order for a robust evaluation to proceed.

It includes an assessment of the coherence and completeness of the intervention design (evaluability in principle), the availability of data (evaluability in practice), and the usefulness of the potential evaluation. These are framed around 26 questions, set out in Annex 4.

The sections below present the EQs against which the evaluability assessment is made. The EQs are grouped by ‘evaluation module’ to provide an organizing framework and structure to the assessment, as follows: (1) right things (design); (2) right way (implementation); (3) right results; and (4) learning.

Evaluability in principle is dealt with entirely under Module 1: right things (design). Evaluability in practice and usefulness are discussed under each of the modules. A detailed description of the evaluability assessment methodology and process is provided in Annex 4, with findings presented in Annex 6.

2.1 Right things – Design

Table 1 sets out the list of EQs within the right things (design) module. The evaluability assessment is conducted on these EQs. The final set of EQs – presented in Section 3.2 – has been somewhat revised based on the findings of the evaluability assessment.

Table 1 - EQs used for evaluability assessment (Module 1)

No.	EQs
1	Is the intervention design and logic underpinning the COVAX Facility and AMC clear, relevant, evidence-based and understood by all stakeholders?
1.1	To what extent and how did external stakeholders and COVAX partners contribute to the original program design, and what impact did this have?
1.2	How effective and appropriate is the design of the COVAX Facility and AMC, including proposed market shaping strategies, to achieving the intervention outcomes and goals? A - To what extent does the intervention logic capture the geopolitical context shaping supply, demand and access to COVID-19 vaccines (including related to intellectual property rights and patents, trade secrets and transparency, and sharing of data and technology)? B - How strategic and appropriate were the choices and trade-offs made in designing the intervention?
1.3	What assumptions underpin the intervention logic, and have they been upheld?

Evaluability in principle: The evaluability assessment found that the COVAX Facility and COVAX AMC design is complicated but coherent. Further work is required to clarify all areas of the intervention logic to ensure it is fully evaluable. The COVAX Facility and COVAX AMC is a system that encompasses many interacting global agents, serving a range of different functions across a number of sectors, requiring

⁷ This aligns with Itad’s understanding of evaluability, which is based on the Organisation for Economic Co-operation and Development’s Development Assistance Committee (OECD DAC) (2002) definition – the ‘extent to which an activity or a program can be evaluated in a reliable and credible fashion’. (oecd.org/dac/evaluation/2754804.pdf, p. 21)

feedback from recipient countries and communities to refine ideas and adjust approaches. Drawing on a range of literature in this area, the system can be usefully framed as one that moves from being ‘complicated’ at the activity and output end of the results chain to one that is increasingly ‘complex’ as it progresses towards impact.⁸ (Annex 7 provides more details.)

A ToC for the COVAX Facility and COVAX AMC has been developed by Gavi which well represents the primary areas of responsibility for each partner but does not elaborate on the causal pathways for the specific programmatic components of the COVAX Facility and COVAX AMC (i.e. resource mobilization, market shaping, procurement and delivery, equitable allocation, and country readiness and delivery (CRD)), and nor does it comprehensively include assumptions.⁹ Another version of the ToC was developed by the evaluation team to further elaborate on the intervention causal pathways; we refer to this as the ‘evaluation ToC’ (see Annex 8). This has benefited from feedback by the ELU, but the evaluability assessment did not include the planned participatory exercise with wider Office of the COVAX Facility staff to systematically explore the ToC, to document assumptions, and to build consensus around it. This workshop should take place at the outset of the proposed formative review and baseline study to ensure that the ToC is sufficiently well developed to be evaluable.

Despite the uncertain context, emergency response and unprecedented approach employed by COVAX, the overall intervention logic and causal chain presented in the evaluation ToC is clear and coherent. However, specific components of the ToC are not. For instance, the COVAX vision of ‘end the acute phase of the pandemic by the end of 2021’ was never clearly defined nor plausible.

Evaluability in practice: There is sufficient data available to assess the relevance, coherence and appropriateness of COVAX Facility and COVAX AMC design. There is substantial internal and external documentation available explaining the intervention design – original and evolving objectives, design choices, trade-offs and assumptions – and causal pathways from inputs through to impact.¹⁰ Internal stakeholders, including COVAX implementing partner staff and experts involved in the original design, are largely still engaged and available for interview. Various other stakeholders, including participating countries, civil society representatives, regional stakeholders, vaccine manufacturers, researchers and policymakers are also available to inform a rounded understanding of the political and economic context of the pandemic, the response, and how the COVAX Facility and COVAX AMC design responded to external challenges and opportunities. However, all stakeholders, particularly the staff of COVAX implementing partners and participating country representatives, are extremely busy and will have limited time to engage with the evaluation, although through the evaluability assessment they have indicated strong interest and willingness to do so.

An important component of the evaluability assessment is to consider the potential to use counterfactual analysis.¹¹ While counterfactual analysis could theoretically support a number of areas of the evaluation, it is difficult to define a counterfactual for the COVAX Facility and COVAX AMC, due to its unique character as the first and only global procurement and delivery mechanism. Counterfactuals where the distribution of COVID-19 vaccines are left solely to market forces or where the COVAX implementing partners had not come together to collaborate are not convincing, primarily as these partners were already collaborating on vaccine access prior to the pandemic and it is unrealistic to consider that they would not have done so for the biggest public health emergency in a lifetime. More realistic is a counterfactual where the organizing governance and management functions of COVAX, and specifically the Office of the COVAX Facility, were not established to formalize ‘COVAX’ as an entity and where, for instance, COVID-19 vaccines were

⁸ For instance, using the Stacey matrix (Zimmerman, B.(2001). *Ralph Stacey’s Agreement & Certainty Matrix*. Edge-Ware Aides. Toronto: York University) and David Snowden’s Cynefin framework (Snowden, D. J. and Boone, M. E. (2007). *A Leader’s Framework for Decision Making*. Harvard Business Review, November edition. <https://hbr.org/2007/11/a-leaders-framework-for-decision-making>).

⁹ Although the intervention logic and overall COVAX Facility design were agreed at the COVAX launch in April 2020, a ToC was drafted later, during implementation. The first draft was presented to the Gavi Board in December 2020 and served to develop a reporting framework and indicators; a second draft ToC was developed in June 2021 to frame the multistage evaluation. A next version, integrating the COVAX 2022 strategy, is under development.

¹⁰ These include updates for Gavi technical and governance bodies (Board, Program and Policy Committee), investment cases for prospective AMC donors and self-financing participants.

¹¹ Counterfactual analysis explores what would have happened in the absence of an intervention.

incorporated into Gavi's existing portfolio and business model, without any expansion beyond Gavi-eligible countries. Such a counterfactual may have some merit but is likely to be difficult to conceptualize and operationalize for analysis. More practical would be a narrower counterfactual where we consider how different design options across specific programmatic components would have played out ('what if'), recognizing that the COVAX design was relatively simple when it started and became more complicated over time in response to stakeholder needs. One such alternative design choice counterfactual may be to understand if/how technology transfer could have been prioritized and included within the intervention design. Comparators also exist and could be applied at a high level (e.g. to compare to the Gavi business model) for the COVAX Facility and COVAX AMC and for-specific strategies such as market shaping, resource mobilization and delivery support.¹²

Usefulness: There is broad stakeholder interest in the evaluation of the COVAX Facility and COVAX AMC design. Stakeholder feedback suggests that Gavi and COVAX partners are primarily interested in improving the design of specific areas of the ToC. Other stakeholders, including the 92 AMC countries (AMC92), donors and the broader development and global health community are more interested in a holistic, independent assessment of the relevance and appropriateness of the overall design and strategic decisions that were taken from the outset, as well as in the processes and level of stakeholder engagement leading to decision making. Particular areas of interest include:

- The design choice to be a global purchasing and allocation mechanism (i.e. for all countries)
- The appropriateness of specific market shaping strategies, combining push and pull mechanisms
- The appropriateness and feasibility of the allocation mechanism design, based on principles of equity and fairness
- The relative balance between efforts focused on scaling vaccine procurement and scaling country-level delivery.

2.2 Right way – Implementation

Table 2 sets out the list of EQs within the right way (implementation) module. The evaluability assessment is conducted on these EQs. The final set of EQs – presented in Section 3.2 – has been somewhat revised based on the findings of the evaluability assessment.

Table 2 - EQs used for evaluability assessment (Module 2)

No.	EQs
2	To what extent have the COVAX Facility and AMC been implemented as intended and efficiently, including in a timely and agile manner?
2.1	What risks/challenges were encountered during the implementation of the COVAX Facility and AMC, and how were these mitigated/resolved?
2.2	How appropriate and relevant are the COVAX Facility and AMC management structures and governance arrangements?
2.3	To what extent were the estimated costs of setting up and implementing the COVAX Facility and COVAX AMC in terms of finances and staff allocation reasonable and appropriate?
2.4	To what extent have relevant external stakeholders been engaged throughout implementation in the manner intended, and what factors affected engagement?
2.5	How effective was the resource mobilization strategy of the COVAX Facility and AMC?

Evaluability in practice: Overall, there is sufficient data available to assess implementation. There are, however, some limitations with the data, which will require significant evaluation work to compensate for. A clear business case exists and, due to a functional COVAX Reporting Framework which is mapped to the COVAX ToC, there are indicators, targets and means of verification for activities and outputs. This Framework is referenced and used to provide regular updates to Gavi technical and governance bodies.¹³

¹² Comparator analysis explores how others have approached and dealt with similar issues.

¹³ For instance, through updates and reports to the Board, PPC, Audit and Finance Committee and risk reports, as well as in internal communications.

There are, however, some limitations of the data available to assess implementation for some areas of the ToC and EQs:

- Despite a wealth of information on implementation progress/decision points, data points are not always aligned with each other, and it is likely that some will be contested. For example:
 - While many decisions related to management structures and governance arrangements (EQ 2.1.1) have been documented in official meetings, some processes and decision points cannot be traced to official meetings or are not aligned with official documentation.
 - Despite data on what and when financial resources were committed and made available (EQ 2.1.3), there is not a fully triangulated account of why any delays occurred. This may be a contentious area but it is also critical to understanding the appropriateness of design.
- There is a need to interpret implementation progress in the context of the COVAX Facility and COVAX AMC being set up as an emergency response to a public health emergency and highly uncertain operating environment.

To overcome these challenges, we see a need for a forensic analysis of timelines, with the EQs being addressed in phases that align to the evolution of the pandemic response. At each phase it will need to be agreed what 'good' looked like, with objective criteria established to assess the appropriateness of decision making. Such work should recognize that COVAX was operating in an emergency mode in an unprecedented situation.

The assessment also highlighted that the wording of some sub-EQs was vague and could lead to misunderstanding/different expectations on the scope of work. To address this, we have suggested amendments to provide greater clarity and focus to the questions. In addition, the current sub-EQs focus only on the operational components of the COVAX Facility and COVAX AMC and do not cover the specific programmatic implementation components (market shaping, procurement and delivery, equitable allocation and CRD). Stakeholder interviews consistently raised the need to interrogate each of these areas in the multi-stage evaluation. Specific questions (EQs 2.2.1–2.2.5) on these areas have been added to the revised questions presented in Section 3.2 and for the evaluation design.

There is scope to use comparator analysis for those EQs focused on identification of risks, management structures and governance arrangements, costs of implementing the COVAX Facility and COVAX AMC, and stakeholder engagement.

Usefulness: There is significant interest from all stakeholder groups on questions related to the operational and programmatic components of implementation. This includes feedback from countries participating in COVAX, civil society representatives, donors and development banks, and national/regional public health ministries and agencies. The interest in these areas is from both a formative perspective (to better understand what has worked well and what has not in terms of implementation, in order to inform course correction) and a summative/accountability perspective (to generate objective assessments of whether implementation has been successful). In relation to the latter, it should be noted that there are significant and varied views on performance among different stakeholders, which reinforces the need to focus on developing and agreeing objective criteria against which progress can be assessed.

Particular areas of interest for the evaluation to explore, as highlighted by stakeholders interviewed, include: the processes in place to communicate and engage with stakeholders; whether internal systems and processes are appropriate to working in an emergency setting, given that they utilize Gavi capacities; clarity of roles and responsibilities and the appropriateness of governance structures to guide decision making and ensure accountability; and the importance of transparency in dealings between vaccine manufacturers, COVAX and participating countries, who have also engaged in bilateral procurement, to achieving COVAX Facility and COVAX AMC goals and objectives.

2.3 Right results

Table 3 sets out the list of EQs within the right results module. The evaluability assessment is conducted on these EQs. The final set of EQs – presented in Section 3.2 – has been somewhat revised based on the findings of the evaluability assessment.

Table 3 - EQs used for evaluability assessment (Module 3)

No.	EQs
3	To what extent have the COVAX Facility and AMC contributed to the achievement of intended outcomes and impact?
3.1	To what extent have the intended intermediate outcomes been achieved? A - Did COVAX Facility market shaping strategies achieve their intended objectives (including rapid development of vaccine portfolio, increased manufacture, pooled demand, secure supply)? B - How well was the COVAX Facility & AMC able to solicit participation of SFP and AMC countries? C - Did the COVAX Facility & AMC allocate vaccines among participating economies and countries as intended? D - Were COVAX Facility & AMC efforts to support vaccination program delivery in-country provided as intended?
3.2	To what extent have the COVAX Facility and AMC achieved (or to what extent is it likely to achieve) intended high-level outcomes and impact? A - Rapidly increased equitable distribution of vaccines across countries, including in fragile and conflict-affected states. B - Delivering vaccination to intended vulnerable populations in participant countries. C - Reducing morbidity, mortality and the socioeconomic impact of the pandemic. D - Ending the acute phase of the COVID-19 pandemic globally.
3.3	How have the COVAX Facility and AMC contributed to the achievement of these outcomes and impact within the global geopolitical and economic landscape of actors involved in development and delivery of COVID-19 vaccines?
3.4	What evidence is there to suggest unintended consequences and results beyond the ToC, including in relation to any effects of the COVAX Facility and AMC on routine immunization efforts?

Evaluability in practice: Overall, there is sufficient data available to assess results, albeit with some anticipated challenges with data availability and the complexity of the evaluand, which complicates analysis of causality. The COVAX Reporting Framework, supplemented by some other documents and information sources (see Annex 9), provides indicators, targets and means of verification to assess progress towards intermediate outcomes, outcomes and impacts across the programmatic areas of the ToC.

There are, however, some gaps in the availability of outcome data on the recipients of COVID-19 vaccines, and specifically whether vaccines are being administered to intended vulnerable populations in participant countries. While the electronic Joint Reporting Form (eJRF) requests disaggregated data by population group, the level of reporting completeness is variable. National Vaccine Deployment Plans (NVDPs) and Vaccine Request Forms articulate detail on whether and how countries intend to prioritize vulnerable populations, and some countries may collect and make available disaggregated vaccine coverage data as part of their national reporting, and/or this may be provided qualitatively to Gavi/partners or in some form of media/Civil Society Organization (CSO) reporting. As such, answers to this part of the EQ may be reliant on estimates and/or the collation of country data outside of official COVAX reporting channels, which may be challenging to collect. In addition, while the COVAX Reporting Framework includes impact metrics on reducing morbidity, mortality and the socioeconomic impact of the pandemic, the methodology is still under development and is unlikely to be able to provide a quarterly snapshot of progress.

In terms of assessing the contribution of the COVAX Facility and COVAX AMC to observed outcomes (EQ 3.3), this will require significant data collection from the various stakeholders engaged to understand – building on the work conducted to assess implementation – the role of the COVAX Facility and COVAX AMC vis-à-vis the role of others, and the context in which the COVAX Facility and COVAX AMC were/are operating. Particular consideration will be required to understand the constraints of country delivery capacity and vaccine hesitancy to the achievement of results. The assessment is also complicated by the complexity of the evaluand – notably with many different project components and multiple interactions of different stakeholders, which makes the attribution of causes to identified effects challenging – as well as the timing of the intervention and the extent to which achievement of overall impacts and goals is realistically expected during the evaluation period. As such, an evaluation approach that can provide rigorous assessment of causality over time, and is based on a thorough understanding of the context and operating environment, is recommended.

There is a significant body of gray and academic literature on COVAX, which provides a starting point for identifying unintended consequences and results (EQ 3.4), as well as efforts by the Office of the COVAX Facility to report on some potential instances (e.g. on vaccine diversion and misuse). On the unintended consequence specified in the question – effects on routine immunization efforts – there is a good level of aggregate data availability and existing literature on disruptions to routine vaccination caused by COVID-19, including by UNICEF and WHO. This is also included within the scope of work for the ongoing evaluation of Gavi’s initial response to COVID-19, which will report findings in late 2022. However, the link between the operationalization of the COVAX Facility and COVAX AMC itself and any disruption to routine immunization is less clear. Possible links to explore may relate to delays in supplying COVID-19 vaccines, damage to Gavi’s reputation, and loss of trust in Gavi’s wider business model and other vaccines, thereby contributing to vaccine hesitancy.

Usefulness: There is significant interest in an assessment of the results of the COVAX Facility and COVAX AMC, and of the reasons why intended results were or were not achieved. A significant body of stakeholders, including AMC92 countries, donors and the broader development and global health community, are primarily interested to understand whether COVAX has been able to influence fair and equitable access to COVID-19 vaccines. This applies across country income categories (i.e. high-income countries (HICs), middle-income countries (MICs) and low-income countries (LICs)), between individual countries, and in the distribution of and access to vaccines within countries (e.g. by geographical area and population group). Multiple stakeholders were also interested to explore the impact of the COVAX Facility and COVAX AMC on routine immunization and Gavi’s routine work.

Stakeholders had a clear appetite to understand whether the objectives of the COVAX Facility and COVAX AMC were achieved. This was most often expressed through the lenses of design and implementation choices: i.e. how the intentions of design elements and the nature of implementation led to and/or affected results, and the ‘what if’ scenarios surrounding decision points. The need to contextualize results was also raised a number of times, accounting for factors outside of Gavi’s control (e.g. related to country delivery capacity and vaccine hesitancy) and the evolving nature of outcomes in response to external events. Staff of the Office of the COVAX Facility, Gavi and COVAX partners expressed a desire for the evaluation to situate such analysis within the context of the emergency response to COVID-19 and to consider the power imbalances and other exogenous factors that have affected COVAX’s ability to deliver results. Many stakeholders were also interested to learn lessons from such analysis to inform future pandemic preparedness, for instance to understand whether the geopolitical and political context needs to change to improve the efficiency and effectiveness of future pandemic responses and if/how ACT-A and COVAX-type mechanisms should be replicated or fundamentally changed as part of this response.

2.4 Learning

Table 4 sets out the list of EQs within the learning module. The evaluability assessment is conducted on these EQs. The final set of EQs – presented in Section 3.2 – has been somewhat revised based on the findings of the evaluability assessment.

Table 4 - EQs used for evaluability assessment (Module 4)

No.	EQs
4	What lessons can be drawn on the design and implementation of the COVAX Facility and AMC?
4.1	To what extent have systems and processes been established to capture, collate and disseminate learning around identified needs/gaps?
4.2	What are the most important barriers and enablers to achieving the outcomes and goals in the COVAX ToC at all levels of implementation?
4.3	What are the priority learnings from implementation of the COVAX Facility and AMC to inform: <ul style="list-style-type: none"> A - course correction for the COVAX Facility and AMC? B - implementation of Gavi 5.0? C - future pandemic preparedness and vaccine innovation and access?
4.4	What can be learned from other agencies/arrangements/contexts and applied to the COVAX Facility and/or AMC for the achievement of intended outcomes and impact?

The findings of the evaluability assessment presented above impact on the quality and availability of lessons learned for several of the learning EQs (4, 4.2, 4.3, and 4.4), as these questions will draw on findings from these components. EQs 4.1 and 4.4 require separate evaluability assessment.

Evaluability in practice: There is sufficient data available to answer the learning EQs, albeit with the caveats outlined in the sections above. Some lessons learned are already available through Program and Policy Committee (PPC) and Board meeting minutes on design and implementation at the global level. Lessons from the first round of vaccine allocation are documented and available in AMC Engagement Group and Shareholders Council meeting reports. Further, the 2021 MM Global Health (MMGH) Consulting review¹⁴ provides learning insight on decision-making processes used in designing COVAX, as well as consideration for future design adjustments.

Barriers to effective implementation have also been documented. For example, the Gavi COVAX AMC Investment Opportunity provides lessons learned on challenges and enablers in six key areas.¹⁵ In addition, a significant amount of externally produced observation and reflection is available in media reports, as well as reports authored by academic institutions and other agencies with an interest in COVID-19 vaccines. This externally produced documentation will help to contextualize and provide triangulation material for lesson-learning. This covers the programmatic areas of the ToC in particular (resource mobilization, market shaping, procurement and delivery, equitable allocation and CRD). There is, however, a gap in the evidence on how implementation in these areas influences the achievement of results, and the evaluation should prioritize data collection and analysis in this area. For this reason, we recommend that EQ 4.2 be retained in the evaluation scope of work but situated within Module 3 on right results.

As highlighted above, another gap relates to lessons learned from participating countries on which population groups are receiving vaccines and how/whether equitable distribution is being achieved. This has implications for the Gavi 5.0 learning priority to understand how to reach zero-dose communities. We understand that there is a potentially rich pool of qualitative learning available through WHO regional teams, who host regular webinars to engage with countries through questions and answers (Q&A). It will be important to access these resources during the multi-stage evaluation. Country-level learning is also available through the Better Immunization Data (BID) Initiative library¹⁶ (a learning network between countries and between regional and global partners) and via additional learning networks.¹⁷ Further, we understand that Gavi country programs and communication staff are engaging with country implementers on a regular basis. The quality of these resources is potentially high, given the direct and real-time nature of their capture. It will be necessary to determine if this data can be triangulated (for instance with civil society) and how evaluation activity can access these lessons learned in a timely and systematic way.

Working sessions with the ELU suggest there is a significant amount of rapid, day-to-day learning that could be drawn on to support the evaluation. This learning takes place organically but is identified by the ELU, which supports the commissioning of rapid reviews and maintains a 'learning library' of the learning materials the ELU team is aware of (although we understand that much day-to-day learning is not necessarily documented or shared with the ELU team in a systematic way). A formative evaluation approach could respond to this gap (a) through stocktake and reflection and (b) by ensuring synthesis products respond to specific learning needs identified in collaboration with the ELU.

In terms of potential learning from comparator agencies/arrangements/contexts, there are a lot of potentially comparable agencies and arrangements to explore for specific programmatic areas of the COVAX Facility and COVAX AMC model – i.e. resource mobilization, market shaping, procurement and delivery, equitable allocation and CRD – with much documentation available online to facilitate analysis. As such, comparator analysis could be conducted within Modules 1 and 2, and learning from these analyses synthesized for EQ 4.4. There is also felt to be scope to learn from experiences across country contexts, and

¹⁴ MM Global Health Consulting. (2021). *Documentation Project: To synthesis core design decisions taken on the COVAX Facility and AMC.*

¹⁵ Gavi. (2021). *One World Protected – The Gavi COVAX AMC Investment Opportunity.* <https://www.gavi.org/sites/default/files/covid/covax/Gavi-COVAX-AMC-Investment-Opportunity.pdf>

¹⁶ BID Initiative. *Resource Library.* <https://bidinitiative.org/resource-library/>

¹⁷ E.g. Geneva Learning Foundation, TechNet, etc.

we propose an additional evaluation question to focus on this specifically: *What can be learned from a comparison of countries' experiences of securing maximum possible vaccination supply, and applied to the COVAX Facility and/or AMC for the achievement of intended outcomes and impact?* This additional question would allow exploration of how countries across the income spectrum have responded to the realities of sourcing vaccines differently. This would encompass identifying which agencies and/or arrangements each has drawn down on, or not, and why. We note the potential to increase the scope of this question further to look at country approaches to maximizing vaccine coverage, which would enable analysis of within-country equity (e.g. between geographical areas and population groups and by gender). However, we do not expect this to yield such interesting learning for the COVAX Facility and COVAX AMC, and as such do not propose this to be included within the scope of work.

Usefulness: There is clear demand and need for learning to meet the evaluation purpose and stakeholder needs. This includes generating and disseminating learning, to influence COVAX Facility and COVAX AMC course correction as well as operationalization of the Gavi 5.0 Strategy, and to inform future pandemic preparedness. This includes the need for *transformative learning* in order to challenge, for instance, the context in which some design decisions were taken, whether the COVAX Facility and COVAX AMC were the right mechanisms to tackle the issue of equitable access to COVID-19 vaccines, and what that might mean for future pandemic preparedness.¹⁸

The main challenge related to usefulness is the dynamic context in which the COVAX Facility and COVAX AMC operates. Learning needs and priorities can change from week to week, which presents challenges for ensuring that evaluation work is timely enough to meet those needs. In such a dynamic context, this will require commitment from the ELU and Office of the COVAX Facility to a formative evaluation approach and making good use of anticipated 'learning points' and other meetings. EQ 4.1 – on the strength of Gavi/COVAX Facility and COVAX AMC systems and processes to capture, collate and disseminate learning – is not considered as high a priority as others.

2.5 Overall evaluability

Overall, the assessment, based on a substantial review of the available literature and information systems as well as broad stakeholder engagement, finds the following.

Evaluability in principle

The COVAX Facility and COVAX AMC design is complicated but coherent. Across the many different project components, COVAX implementing partners work in interconnected ways to fulfill roles and responsibilities that facilitate COVAX Facility and COVAX AMC results. The COVAX Facility and COVAX AMC ToC seeks to provide clarity on these areas of responsibility, but does not comprehensively map out causal pathways nor document assumptions related to the intervention itself or the broader context. The 'evaluation ToC' takes this work further but has not been completed. As such, further work is required to clarify all areas of the intervention logic to ensure it is fully evaluable. Periodic changes to the design will need to be fully analyzed through the evaluation in order to understand how and whether these changes are coherent and influencing implementation progress and results over and above the prior design.

Evaluability in practice

Overall, sufficient data is available to assess the design, implementation and results of the COVAX Facility and COVAX AMC to satisfy accountability needs and to generate learning to inform course correction and future pandemic preparedness. Substantial internal and external documentation is available explaining the intervention design – original and evolving objectives, design choices, trade-offs and assumptions – and causal pathways from inputs through to impact; implementation progress; emerging results; and lessons

¹⁸ Transformative learning theory was developed by Jack Mezirow in the late 1900s. He used this theory to describe how people develop and use critical self-reflecting to consider their beliefs and experiences and, over time, change dysfunctional means of seeing the world. Mezirow was interested in people's world views and what leads people to change their particular view of the world. Transformative Learning Theory (Mezirow) - Learning Theories (learning-theories.com).

learned to date, including on barriers to effective implementation. Nonetheless, some decision points are not documented and may be contested, which will require triangulation of multiple data sources. There is a need to interpret implementation progress in the context of the COVAX Facility and COVAX AMC's role in the pandemic response and the wider operating environment, which has been highly political and dynamic, having evolved substantially over time. As such, it will be important for the evaluation to determine what 'good' looked like at different points in time, recognizing that COVAX was operating in emergency mode in response to an unprecedented situation. Given the complexity of the COVAX Facility and COVAX AMC design and its operating environment, assessing its contribution to observed results will also be challenging and require significant analysis and triangulation of data sources.

Given how recently COVAX was established, key internal and external stakeholders are mostly still engaged and are expected to be able to provide detailed information in response to the EQs and the political and economic context in which COVAX was operating. Accessing these stakeholders through key informant interviews (KIIs) and focus group discussions will be critical to generating the evidence required to answer the EQs robustly, especially those where significant analysis and triangulation are required. While country stakeholders and the staff of COVAX implementing partners are extremely busy and will have limited time to engage with the evaluation, the evaluability assessment process did indicate strong interest and willingness to do so.

There are, however, gaps in the availability of outcome and impact data and some disconnect between the EQs and the evaluation scope of work. There are challenges in obtaining complete data on the targeting and administration of vaccines among intended vulnerable populations in participant countries, and gaps in data regarding the health and socioeconomic impact of the intervention (the methodology for estimating the latter is under development). The evaluability assessment also highlighted that the EQs do not specifically cover all of the programmatic areas of the COVAX Facility and COVAX AMC ToC, i.e. market shaping, procurement and delivery, equitable allocation and CRD. As such, there is some scope for differing expectations on the scope of work.

Usefulness

There is substantial interest in the evaluation across a range of stakeholders. However, stakeholders have different needs and expectations from it. Among the stakeholders interviewed, there was an even split of those who saw the evaluation's primary use as being to generate learning and those who saw it as being to serve an accountability purpose.¹⁹ More specifically, COVAX implementing partners are most in need of – in the short term at least – rapid learning to inform course correction. As noted above, the COVAX Facility and COVAX AMC design is expected to continue evolving, and there is potential for the evaluation to influence and inform design decision making. The Gavi Board requires that the evaluation be used as part of good governance to demonstrate accountability for the use of ODA and achievement of results to donors, investors and countries participating in COVAX. This is broadly aligned to a strong expectation from many other stakeholders for a holistic evaluation that seeks to understand whether COVAX has been able to overcome power imbalances to ensure equitable global access to COVID-19 vaccines and to generate transformative learning for future pandemic preparedness.

¹⁹ Themes of particular interest across accountability and learning include equity, sustainability and the implications of COVAX for Gavi's 'routine' business model. Within learning objectives, learning for course correction and for future pandemic responses is deemed most important, with a desire for lessons to inform course correction more urgently. This was echoed in online survey responses. Around a third of those interviewed are keen to see detailed learning on programmatic areas, especially around market shaping but also more broadly on learning from end to end of the COVAX Facility and COVAX AMC change pathway. Another third of key informants are interested to learn about the organizational and governance mechanisms in place, particularly to understand whether the right mix of partners is engaged and whether the division of labor is appropriate. A quarter of key informants suggested the need for the evaluation to have a broader focus, not just exploring COVAX but including exploration of the wider operating environment, including within ACT-A. Other areas of need, mentioned less often, include: exploring communication; and engagement with AMC countries.

2.6 Recommendations to strengthen evaluability

A number of recommendations are drawn from the evaluability assessment and taken forward into the evaluation design:

1. Consider ways for the evaluation to balance different stakeholder needs and expectations from the evaluation. While this evaluation can help answer part of the question on whether COVAX has been able to ensure equitable global access to COVID-19 vaccines – and can aid lesson-learning for future pandemic preparedness – its focus on just the COVAX Facility and COVAX AMC will not allow for a full answer. The evaluation can, however, align to other evaluation processes conducted on similar topics and other areas of COVAX in order to learn lessons more holistically and to seek to understand how and whether equity (i) has been a central principle in the design of the COVAX Facility and COVAX AMC (equity in process), and (ii) is reflected in the results achieved (equity in outcomes).²⁰ Equity should be considered in at least three ways:
 - in the distribution of and access to vaccines across country income categories (i.e. HICs, MICs and LICs);
 - in the distribution of and access to vaccines between individual countries; and
 - in the distribution of and access to vaccines within countries, such as between geographical areas and population groups and by gender.²¹
2. Further develop the COVAX Facility and COVAX AMC ToC to elaborate on the causal pathways and comprehensively include assumptions – explicit, implicit, documented and undocumented. This should capture all previous and future design iterations. This process is underway and is a core component of the proposed evaluation design.
3. The evaluation is focused on Gavi and the COVAX Facility and COVAX AMC, although it is unlikely to be possible or most helpful to evaluate these in isolation. Rather, the evaluation should consider the interconnectedness of roles, responsibilities and ways of working between agencies to facilitate COVAX Facility and COVAX AMC results.
4. Ensure that the evaluation considers the COVAX Facility and COVAX AMC in the context of COVAX and ACT-A more generally and of the geopolitical and wider contextual factors at play. This will necessarily involve taking into consideration factors both within and outside of Gavi's direct control, and factors over which it has both higher and lower levels of control and can be held accountable for (see Annex 7).
5. Clarify the wording of some proposed EQs to ensure questions are evaluable and avoid misunderstanding/different expectations on the scope of work. We have sought to do this in the revised set of EQs within the proposed evaluation design in a number of ways, including the following:
 - A set of EQs has been included in the revised set of EQs for the evaluation design to understand implementation of specific programmatic implementation components (resource mobilization, market shaping, procurement and delivery, equitable allocation and CRD).
 - Deprioritize EQ 4.1 – on the strength of Gavi/COVAX Facility and COVAX AMC systems and process to capture, collate and disseminate learning – from the evaluation scope of work, but recommend to Gavi that the monitoring, evaluation and learning (MEL) function has sufficient capacity to fulfill these functions on an ongoing basis.
 - Shift EQ 4.2 to 'right results' module to ensure evidence and findings are generated on how barriers and enablers to outcome achievement relate to the change pathways implicit in the COVAX Facility and COVAX AMC ToC and to factors outside of Gavi's direct control.

²⁰ For examples on equity in outcomes, see UNICEF guidance (Section 3.1).

https://evalpartners.org/sites/default/files/EWP5_Equity_focused_evaluations.pdf

²¹ This is beyond the COVAX Facility and COVAX AMC's sphere of responsibility and control, and may not be the focus of the evaluation.

- Include an additional learning EQ to understand what can be learned from a comparison of country experiences of securing maximum possible vaccination supply and applied to the COVAX Facility and COVAX AMC for the achievement of intended outcomes and impact.
6. Ensure that the evaluation design is cognizant of limited stakeholder availability to engage with the evaluation and builds in sufficient flexibility to secure both broad-based inputs and the inputs of key stakeholders from COVAX implementing partners and participating countries.

These recommendations are made to the Gavi Secretariat and Office of the COVAX Facility to strengthen evaluability:

7. Strengthen data availability on the recipients of COVID-19 vaccines, including disaggregation by vulnerable populations in participant countries, by taking steps to improve eJRF reporting completeness, triangulating data from other sources, and/or undertaking special studies in a sample of countries.
8. Finalize the methodology for impact metrics on reducing morbidity, mortality and the socioeconomic impact of the pandemic.

3. Multi-stage evaluation design

This section, developed based on the findings of the evaluability assessment, discusses the evaluation design. This is a multi-stage evaluation over a 10-year horizon, in line with the initially envisaged life span for the COVAX Facility and COVAX AMC. Given that the intention is for the multi-stage evaluation (possibly following the formative review and baseline study) to be put out to tender, it is anticipated that, following normal procurement processes, elaboration of the evaluation approach and methodology will form a scoring part of the technical proposal in the tenderers' response. This would then be further developed in detail in the winning bidder's own inception phase.

Thus the scope of this section is not a detailed methodological prescription for conducting the multi-stage evaluation. It sets out: the purpose, principles and strategic direction of the multi-stage evaluation; the scope of work; proposed revisions to the EQs; and the broad outline of a suggested approach, including elements of its implementation.

Throughout the section a series of options and recommendations are presented and, based on the recommended course of action, further options and recommendations are made. These are summarized in Annex 19.

3.1 Purpose and principles of the multi-stage evaluation

Across all stakeholders, the COVAX Facility and COVAX AMC needs to be evaluated, for three main reasons:

- Learning is central to a flexible and adaptive approach to tackling complex problems in a dynamic environment to support course correction
- Good governance – accountability and transparency
- Learning to inform future pandemic preparedness efforts.

In essence, these are accountability and/or learning purposes. They should not be seen as a dichotomy – an evaluation can be designed to serve both, for instance with learning used immediately to improve management and implementation, and with learning generated retrospectively at the end of a program to conclusively inform a policy, another funding initiative, or a future response.

The value of evaluation is predicated on it being useful and used. Given the institutional context for the COVAX Facility and COVAX AMC and its multiple stakeholders, the multi-stage evaluation needs to promote learning and accountability at all levels. Given the significance of its role in responding to the COVID-19



pandemic, there is enormous stakeholder interest in the COVAX Facility and COVAX AMC. Its evaluation has a range of stakeholders, who are the target audience for all or part of the evidence and learning generated. As highlighted above, each of these stakeholders has different interests in the multi-stage evaluation. (A communication and learning plan is set out in Annex 16, and a dissemination plan is set out in Annex 17.) The following are priority users and uses of the evaluation:

- Gavi Board, primarily to hold the Secretariat and Office of the COVAX Facility to account for their role in implementing the COVAX Facility and AMC, alongside other implementing partners, for the use of ODA and achievement of results to donors, investors and all countries participating in COVAX.
- COVAX implementing partners, particularly the Gavi Secretariat and Office of the COVAX Facility to enable (a) rigorous testing, learning and adjustment of the complex COVAX Facility and COVAX AMC model to ensure fitness for purpose within its operating environment and optimize the conditions for desired results to be achieved; and (b) comprehensive tracking of the progress and contribution of the COVAX Facility and COVAX AMC to intended results, with explanations of how and why this is or is not being achieved.
- The global health community writ large, including AMC countries, with a proactive focus on equity, to report objectively on the extent to which COVAX has been able to address power imbalances to ensure equitable access to COVID-19 vaccines and inform future pandemic preparedness.



3.2 Revised EQs

Table 5 sets out the list of core EQs which are designed to apply across the stages of the multi-stage evaluation. These have been revised from those presented in the RfP, based on the findings of the evaluability assessment, as discussed above and in Annex 4. As with the evaluability assessment, they have also been grouped by evaluation module as follows, which is discussed in Section 3.3: (1) right things (design); (2) right way (implementation); (3) right results; and (4) learning. The table also responds to recommendation 1 of the evaluability assessment by highlighting how equity will be considered in both the design of the COVAX Facility and COVAX AMC (equity in process) and the results achieved (equity in outcomes).

Table 5 - Revised core EQs for the multi-stage evaluation

Evaluation module	EQ #	EQs (Bold = headline EQ)	Description/justification for revision	How equity ²² will be considered
 1. Right things: Design	1	Is the design and intervention logic underpinning the COVAX Facility and AMC clear, relevant, inclusive and appropriate to enable achievement of intended outcomes and impact?	Condensed	Assessment of appropriateness will center around whether the design is aligned to the principles of equity and fairness
	1.1	To what extent are the overall design of the COVAX Facility and AMC and specific strategies clearly justified and documented, and is the overall design clear and coherent?	Focus on design clarity: is there an (updated) ToC, are strategic choices clear	Exploring the implications of design choices for equity and how equity considerations were factored into prioritization decisions
	1.2	Recognizing the dynamic nature of the pandemic and geopolitical context, what design revisions were made since the original design, and why?	Focus on design revision: rationale	
	1.3	How did external stakeholders and COVAX partners contribute to the original design, and subsequent design revisions of the COVAX Facility and AMC, and what impact did this have?	Focus on design responsiveness: participation	Exploring whether all major stakeholder groups were sufficiently engaged in design decision-making processes and the implications of this for how equity considerations were prioritized
	1.4	Are any design revisions needed for course correction? What are the design lessons for future pandemic responses?	Focus on design lessons – for now and later	Exploring the implications of design choices for equity
 2. Right way: Implementation	2	Have the COVAX Facility and AMC been successfully implemented?	Focus more broadly on implementation, with specifics of implementation covered under operational and programmatic domains	Assessment to understand whether equity in design is being operationalized as intended across operational and programmatic functions/components
	2.1	Have the COVAX Facility and AMC been operationalized successfully? (operational domain)	2.1 and sub-questions 2.2.1–2.1.4 focus on operational domain	
	2.1.1	Have the COVAX Facility and AMC management structures/governance arrangements been fit for purpose?	Focus on appropriateness of management and governance	Exploring the implications of management and governance choices on equity – whether all major stakeholder groups were sufficiently engaged in key processes
	2.1.2	Have the COVAX Facility and AMC risk management processes been fit for purpose?	Focus on appropriateness of risk management processes rather than specific risks	Analysis of the balance struck between managing financial risk and programmatic risk (i.e. the risk of not implementing or achieving programmatic targets) and the implications of this for equity
	2.1.3	To what extent were the estimated costs of setting up and implementing the COVAX Facility and COVAX AMC in terms of finances and staff allocation reasonable and appropriate?	Focus on how appropriate costs were in relation to scope and scale of work	Consideration of implications or trade-offs for equity
	2.1.4	Has the level of stakeholder engagement and communication been appropriate?	Focus on appropriateness of engagement rather than extent of engagement	Exploring whether all major stakeholder groups were sufficiently engaged in implementation decision-making processes and the implications of this for how equity considerations have been prioritized
	2.2	To what extent have the specific COVAX Facility and AMC programmatic/intervention areas been implemented successfully? (programmatic domain)	2.2 and sub-questions focus on the programmatic domain. These areas will be considered across all evaluation modules	

²² Equity and fairness are at the heart of the COVAX Facility and COVAX AMC's design and can be considered in at least three ways: in the distribution of and access to vaccines across country income categories (i.e. HICs, MICs and LICs); in the distribution of and access to vaccines between individual countries; and in the distribution of and access to vaccines within countries, such as between geographical areas and population groups and by gender.

	2.2.1	To what extent has an appropriate resource mobilization strategy been established and implemented to secure adequate resources for full and timely implementation of intended activities?	Adapted from previous EQ 2.5	Exploring whether/how resource mobilization enabled/ hampered equity goals to be met
	2.2.2	To what extent have market shaping activities been implemented to ensure that COVID-19 vaccines are accessible and affordable for lower-income countries?		Exploring whether products focused on reasonably meet the needs of all stakeholders
	2.2.3	To what extent have the COVAX Facility and AMC supported procurement and delivery functions to ensure that COVID-19 vaccines are provided to participants as planned?		
	2.2.4	To what extent have the COVAX Facility and AMC supported the operationalization of the allocation mechanism to ensure a fair and equitable distribution of COVID-19 vaccines?	Added to address programmatic component of the ToC	Explicit focus on equity, including through analysis of cross-country and within-country allocation, distribution and access
	2.2.5	To what extent have the COVAX Facility and AMC supported CRD to facilitate the rollout of COVID-19 vaccines at the scale required to achieve intended outcomes and impact?		
	3	To what extent have the COVAX Facility and AMC, alongside the roles of other COVAX implementing partners, contributed to the achievement of intended outcomes and impact within the geopolitical and economic landscape?		Analysis to understand whether/how equity is being achieved in outcomes
3. Right results: Outcomes and impact	3.1	To what extent have the COVAX Facility and AMC intended intermediate outcomes been achieved?	Focus on results under Gavi control	Explicit focus on equity, including through analysis of cross-country and within-country allocation, distribution and access
	3.2	To what extent have the COVAX Facility and AMC intended outcomes and goals been achieved?	Focus on results beyond Gavi control	
	3.3	What is the evidence to suggest that the COVAX Facility and AMC incurred unintended consequences and results beyond the ToC, and what were the implications?	Focus on unintended results. Reframed to broaden out interest to any possible unintended consequences	Analysis of the equity implications of any unintended consequences (e.g. impact on health systems and access, vaccine hesitancy spilling over to routine immunization, etc.)
	3.4	How have the COVAX Facility and AMC, alongside the roles of other COVAX implementing partners, contributed to achievement of outcomes and impacts within the global geopolitical and economic landscape?	Focus on contribution to impact	Exploring whether intervention has contributed to improvements in equitable cross-country and within-country allocation, distribution and access; and barriers/enablers to this
	3.5	What are the most important barriers and enablers to achieving the outcomes and goals in the COVAX ToC at all levels of implementation?	Understanding barriers and enablers to intended change	
		4	What lessons can be drawn from the design and implementation of the COVAX Facility and COVAX AMC for course correction, Gavi 5.0, and future pandemic responses?	
4. Learning	4.1	What are the most important lessons learned through design and implementation experience that have implications for COVAX Facility and AMC course correction?	None	
	4.2	What are the most important lessons learned through design and implementation experience that have implications for Gavi 5.0?	None	Summary of design and implementation findings and learnings of relevance to equity
	4.3	What are the most important lessons learned through design and implementation experience that have implications for future pandemic responses?	None	
	4.4	What can be learned from other agencies/arrangements/contexts and applied to the COVAX Facility and/or AMC for the achievement of outcomes and impact?	Focus on comparators	
	4.5	What can be learned from a comparison of countries' experiences of securing maximum possible vaccination supply and coverage, and applied to the COVAX Facility and AMC for the achievement of outcomes and impact?	Focus on country realities	Analysis will focus on how the principles of equity and fairness are realized from other settings

3.3 Strategic direction and methodological approach for the multi-stage evaluation

3.3.1 Overarching evaluation structure and design

To meet stakeholder needs, the evaluation approach should blend the principles of both (i) a periodic and phased formative-summative evaluation and (ii) real-time evaluation. The findings of the evaluability assessment indicate a strong need and stakeholder demand (particularly from the Gavi Secretariat, Office of the COVAX Facility and other implementing partners – i.e. CEPI, UNICEF and WHO) for an evaluation function that uses evidence and supports rapid learning to support future design iterations. A ‘real-time evaluation’ approach would be suitable to meet this need – this is an evaluation that would collect data and report back findings in real time, or as quickly as practicable.²³

The EQs, however, stemming from the Gavi Board requirement (but also the expressed desire from stakeholders external to COVAX) for a fully independent and robust evaluation that meets an accountability objective, would require a more holistic evaluation of what has worked well and less well in the design, set-up and implementation of the COVAX Facility and COVAX AMC, and in terms of what results have been achieved. A periodic and phased formative-summative²⁴ evaluation approach would typically meet this need – i.e. conducted at predetermined time intervals, where the scope shifts from design and early implementation at the outset and places more weight on assessing results over time.²⁵ Such an approach would also be appropriate for generating learning to inform course correction and transformative learning for future pandemic preparedness. However, such learning may not always come at the right times to inform course correction in a highly dynamic environment.

As such, a blended approach would be most appropriate.²⁶ This should enable the evaluation of specific components of the COVAX Facility and COVAX AMC ToC in real time, as well as providing a coherent evaluation narrative on its overall contribution to outcomes and impact. In so doing, the approach can be learning and utilization-focused while still able to cover the entire ToC and scope of work (as required), provide full responses to the EQs, and meet the stated evaluation purpose on accountability. In practice, this will involve:

- periodic baseline, midterm and end-term evaluation exercises covering the full scope of work, including stage-specific questions (nested within the core EQs) of particular relevance to each point in time an exercise is conducted²⁷

²³ This would involve a series of real-time evaluations conducted on specific parts or causal pathways of the ToC, with a strong focus on generating learning (single, double and triple loop) to inform immediate course correction. For a comprehensive description, see <https://www.betterevaluation.org/sites/default/files/Real%20time%20evaluation%20paper%20Dec%202020%20FINAL.pdf>

²⁴ Formative evaluation work would be designed to inform ongoing implementation. It must feed into learning systems and processes that allow course correction. Summative evaluation work would provide a regular evaluative process running from year to the end-term – i.e. the period from when initial outcomes should be emerging to when substantive impacts start to be seen. In complex adaptive systems, reflexive and social learning is necessary to understand non-linear effects – the evaluation will contribute to this ongoing learning and sense-making: ‘In evaluating complex interventions we should settle for constantly improving understanding and practice by focusing on reducing key uncertainties’. Ling, T. (2012). *Evaluating complex and unfolding interventions in real time*. *Evaluation*, 18 (1), 79–91.

²⁵ This approach would start with a formative review and baseline study, followed by periodic evaluation exercises (e.g. annually, biannually, or just once through a midterm evaluation) and finish with an end-term evaluation.

²⁶ Itad has extensive experience in conducting large multi-stage evaluations which accompany the implementation of complex projects, where evidence is often phased and formative during implementation and builds towards a final summative assessment. For example, Itad’s evaluation of the Global Challenges Research Fund (GCRF) – available from <https://www.itad.com/project/evaluation-of-the-global-challenges-research-fund/> – utilizes a series of modules which progress and cumulatively build the evidence base. The first stage is about pre-conditions for success, moving in time to consider early-stage results (outputs) and then towards outcomes and impacts. Another example was Itad’s evaluation of the Adolescents 360 programme – available from <https://www.itad.com/project/evaluation-of-adolescents-360/>

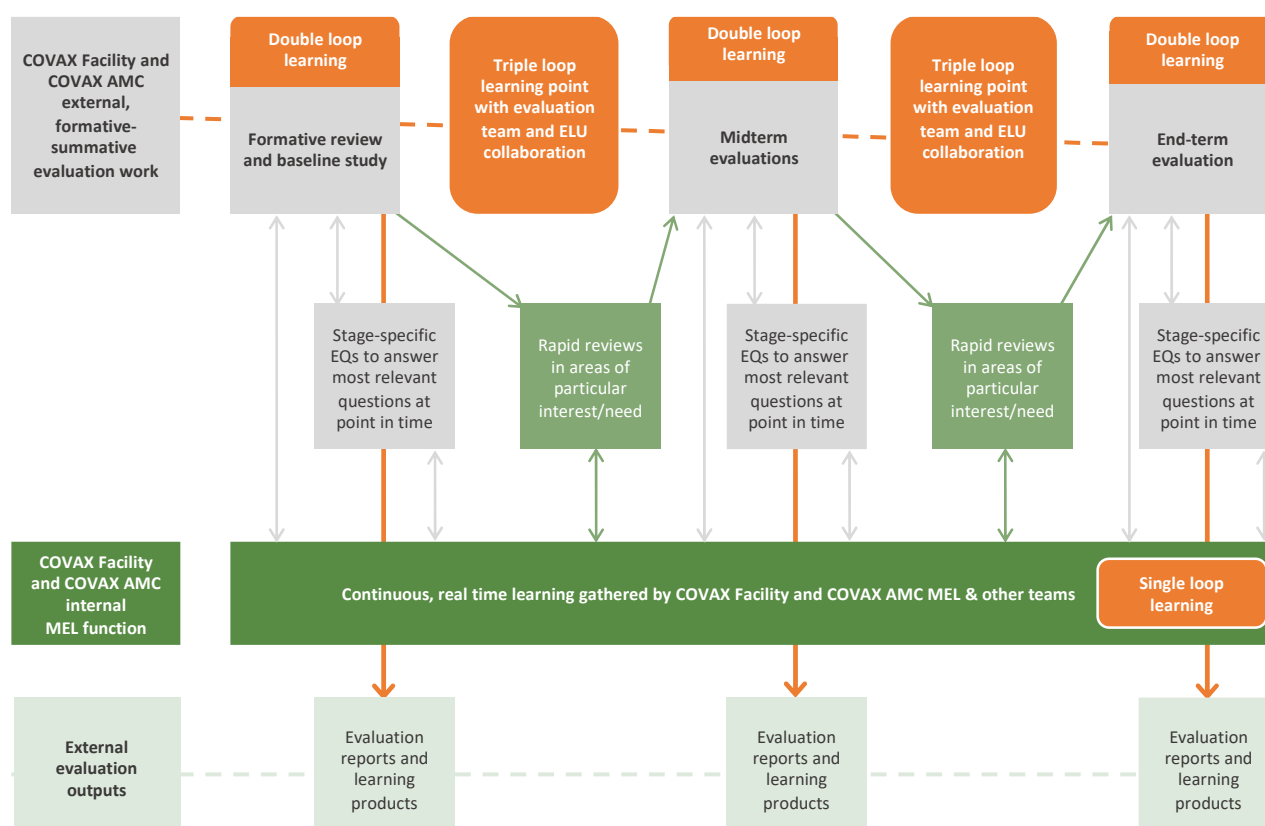
²⁷ The core EQs set out in Table 5 are framed at a relatively high level and are designed to stay fairly constant over the entire multi-stage evaluation (although more could be added, as needed). These will be answered through the formative-summative evaluations over time. Stage-specific EQs, nested within each of the core EQs, will be framed for each formative-summative evaluation process. These EQs will ensure that the evaluation is answering the most relevant questions and is focused on those questions that are possible to answer at any given moment in time.

- the flexibility to conduct ‘rapid reviews’ focused on specific parts of the ToC where learning is needed quickly (e.g. to address operational issues and influence rapid course correction).

Figure 1 illustrates the envisaged complimentary relationship between the formative-summative evaluation work, stage-specific EQs, rapid reviews, and wider COVAX Facility and COVAX AMC MEL function, and highlights the type of learning that could be generated at each stage.²⁸ Annex 14 provides more detail on how rapid reviews complement and add value to the formative-summative evaluations and continuous learning function.

We note the importance of having a continuous learning function to generating, collating (i.e. through the learning library), analyzing and using learning for immediate course correction and future pandemic preparedness. The evaluation can support this function through synthesis across all evaluation activity and the development of synthesis learning products, but the function should be led by the Office of the COVAX Facility/Gavi ELU. An approach for the evaluators and ELU to work together is set out in Annex 7.

Figure 1 – Complementarity between both (i) periodic and phased formative-summative evaluation and (ii) rapid reviews



A complexity-aware, mixed-method design is most appropriate. The COVAX Facility and COVAX AMC system is ‘complicated’ in and of itself and ‘complex’ as it engages in the real world to produce results. The scope of the evaluation (which must take account of the context, factors within and outside of Gavi’s

For example, questions about impact cannot generally be answered in the early years as there is a series of activity, output and uptake processes to go through to get to impact.

²⁸ Single loop: Identifying discrepancies between planned and actual activities and results and suggesting ways to improve compliance, but without necessarily addressing the cause. Double loop: Exploring root causes of problems to revisit ToC assumptions and adjust systems, processes and/or capacities for implementation. Triple loop: Reviewing what evidence is being used and exploring how learning action happens to support decision making. Tarek, M. (2020, December 12). *06 Single Double Triple Loop Learning*. [Video]. YouTube. <https://www.youtube.com/watch?v=iWHOSnrsuPo>; Rogers, P. (2021, April 15). *Why do we need more real-time evaluation?* Better Evaluation. <https://www.betterevaluation.org/en/blog/why-do-we-need-more-real-time-evaluation>

direct control, and factors over which it has both higher and lower levels of control and can be held accountable for) requires a complexity-aware design. This dictates that some approaches will be more relevant and feasible to application than others. Moreover, the type of questions being asked of the evaluation are a mix of ‘how well’, ‘how much’ and ‘how’ questions. The types of EQs, the demand for findings at different times for different uses, and the scale of the evaluation mean that no single method or approach will fully address the requirements of the evaluation. A mixed-method design is required.

3.3.2 Overarching evaluation approach and method

It is recommended that the evaluation design be theory-based. Theory-based approaches to evaluation use an explicit ToC to draw conclusions about whether and how an intervention/program contributed to observed results.²⁹ A ToC provides a conceptual analytical model of how an intervention is expected to produce results. Alongside the inputs and sequence of events that lead to results (i.e. the intervention logic), the ToC describes the mechanisms of change, as well as the assumptions, risks and context that support or hinder the achievement of intended outcomes. As such, a ToC allows evaluators to better understand causal linkages and test these to verify the theory. Theory-based approaches are well suited to (and were originally developed to tackle) the evaluation of more complicated and complex interventions, and complement – and can be used in combination with – most evaluation methods and data collection techniques.

Annex 8 provides a detailed description of the ‘evaluation’ ToC constructed as part of the evaluability assessment for the COVAX Facility and COVAX AMC. This ‘version 0’ ToC presents the core activities and outputs of the COVAX Facility and COVAX AMC, plus intermediate and higher-level outcomes. The ToC also describes the main programmatic activity areas of the COVAX Facility and COVAX AMC (i.e. resource mobilization, market shaping, equitable allocation and CRD) and captures the higher-level goals (i.e. health and socioeconomic change) to which the COVAX Facility and COVAX AMC are intended to contribute. Once the ToC is fully developed (as part of the baseline process), the final EQs will be mapped to the ToC to enable the systematic testing of the theory to understand what is and is not working as intended over time. Importantly, as is highlighted in Annex 8, we recognize that the COVAX Facility and COVAX AMC design and the context in which they are operating have evolved substantially over time and are likely to continue to do so. As such, and to ensure that the evaluation findings are as current as practicable, the ToC will require frequent revision and updating throughout the evaluation process.

To assess COVAX Facility and COVAX AMC results, the evaluation should adopt a generative causation approach. To meet the evaluation purpose, as set out in Section 3.1, the evaluation will need to make causal inference – i.e. to establish whether and how implementation of the COVAX Facility and AMC has contributed to observed results. As set out in

²⁹ Treasury Board of Canada Secretariat. (2009). *Theory-Based Approaches to Evaluation: Concepts and Practices*. <http://www.tbs-sct.gc.ca/cee/tbae-aeat/tbae-aeatb-eng.asp>

Table 6 (and described in more detail in Annex 7), there are four types of approach for establishing cause-and-effect linkages.

Table 6 - Four types of approach for causal inference³⁰

Approach	Aspect of causal relationship	Type of causal question	Description of causal mechanism
Regularity framework ³¹	Association between single cause and effect	Did the intervention cause the effect? How much is the net effect of the intervention?	None
Counterfactual framework ³²			None
Configurational ³³	Association between configurations of conditions and effects; description of causal mechanism	What configurations of factors are necessary and/or sufficient for the effect?	Only basic ingredients are described: conditions, their combinations and disjunctions
Generative causation	Description of causal mechanism	How was the effect produced? How did it come about?	In-depth

Regularity and counterfactual frameworks are ruled out as the principal methodological approach since such approaches do not deal well with complexity, nor provide sufficient insight into the causal mechanism (i.e. how and why the mechanisms in question, operating in the prevailing context, generate social behavior and explain how outcomes were achieved). *Configurational approaches* are also ruled out since such approaches identify the ingredients of the causal mechanism but do not provide in-depth insight of how and why outcomes were achieved. Such insight is critical to answering the EQs and understanding how and why the COVAX Facility and COVAX AMC have contributed to the achievement of intended outcomes and goals. Nonetheless, these methods may have some merit for inclusion in the evaluation approach in order to answer specific EQs or parts of EQs, likely in later evaluation phases when sufficient data on outcomes is available to facilitate the level of statistical analysis required.

Generative causation approaches are designed to identify the mechanisms and contexts that explain outcome patterns and so provide the most complete approach to causal explanation. These approaches rely on generating a strong theory of how the mechanism(s) interacts in the prevailing context to achieve the intended outcomes. For instance, we would expect to consider through this approach how the COVAX Facility acted to influence market shaping and was enabled and/or hampered by various contextual factors, such as those that related to vaccine manufacturers, regulators, policymakers, and other purchasers. This works with a theory-based approach to examine the extent to which and how an intervention has produced or influenced observed results.³⁴

Within the family of generative causation, theory-based evaluation (TBE) approaches, the overall multi-stage evaluation should primarily utilize contribution analysis and process tracing as the most practical methods to implement and directly answer the EQs. While a mixed-method design will be appropriate, there are benefits to adopting a consistent overarching overall approach and method, as outlined below. The influential Stern et al. paper on options for evaluation in international development³⁵ identifies two

³⁰ Befani, B. and Mayne, J. (2014). *Process Tracing and Contribution Analysis: A Combined Approach to Generative Causal Inference for Impact Evaluation*. Institute of Development Studies. IDS Bulletin, 45 (6), 17–36. <https://core.ac.uk/download/pdf/43538408.pdf>

³¹ Regularity frameworks that statistically analyze (e.g. through regression) the frequency of association between cause and effect are ruled out since data on outcomes is sparse and such approaches do not provide insights into the causal mechanism (i.e. the mechanisms and contexts that generate social behaviour and explain how and why outcomes were achieved).

³² Counterfactual frameworks determine the difference between two situations identical apart from the intervention in question. However, these quantitative approaches (e.g. randomized control trials) are not feasible since random assignment is not possible. Qualitative approaches are more feasible, yet – as set out in Section 2.1 – there are substantial challenges to defining an appropriate overall counterfactual for the COVAX Facility and COVAX AMC, due to its unique character and the context in which it is operating. Narrower counterfactuals for specific parts of the ToC may help demonstrate causal linkage but will not provide holistic answers to the EQs on their own or provide insight on how and why change occurred.

³³ Configurational approaches identify a number of ‘cases’ with different attributes and seek to understand how the combination of these cases and attributes can explain variations in outcomes across contexts. This can be operationalized through qualitative comparative analysis to determine the conditions that are necessary and sufficient for an outcome to occur. Such approaches identify the ingredients of the causal mechanism but do not provide in-depth insight of how and why outcomes were achieved.

³⁴ Treasury Board of Canada Secretariat. (2021, March 22). *Theory-Based Approaches to Evaluation: Concepts and Practices*. Government of Canada. <https://www.canada.ca/en/treasury-board-secretariat/services/audit-evaluation/evaluation-government-canada/theory-based-approaches-evaluation-concepts-practices.html>

³⁵ Stern, E., Stame, N., Mayne, J., Forss, K., Davies, R. and Befani, B. (2012). *Broadening the Range of Designs and Methods for Impact Evaluations* (Working Paper 38). Department for International Development.

types of approach to TBE that support causal inference – process-oriented and mechanism-oriented – though notes that these are usually inextricably interwoven:

- *Process-oriented*: Follows various causal links in a chain of implementation of an intervention, ‘built around a “theory” that is a set of assumptions about how the intervention achieves its objectives and under what conditions’.³⁶ The most commonly used are contribution analysis and process tracing.
- *Mechanism-based*: In order to make a causal claim, a mechanism that ‘makes things happen’ needs to be identified. But mechanisms do not operate in a vacuum – the interaction with context is important. Mechanism-based evaluation seeks the connection between causes and effects through deep theoretical analysis, based on mid-range theories. This stems from a ‘realist’ perspective, and its most common method is realist evaluation.³⁷

Table 7 provides a quick comparison of contribution analysis and realist evaluation and suggests that either could be used to good effect to answer the EQs. However, the evaluability assessment findings (see Section 2.3), notably around the limited availability of stakeholders to engage with the evaluation, and the ability to directly answer the EQs of interest, suggest that contribution analysis and process tracing will be the most practical and useful methods to implement.

We note, however, the importance of understanding how the context has shaped and influenced design, implementation and results to ensure external validity – i.e. how well findings can be expected to apply to other settings. Our approach to implementing contribution analysis is set out in Section 4.1.3.3 and Annex 12. Approaching the evaluation in this way will involve repeatedly looping back to test evidence against the ToC on how and why change happens, and as such would allow for repeated updates to the ToC to be made across the phases of the evaluation. This approach will generate learning for immediate course correction and will deal well with the dynamic nature of the evaluand design and operating environment. Gaining an in-depth understanding of how well the COVAX Facility and COVAX AMC have worked in the context of the COVID-19 pandemic response will also be useful for generating transformative learning on future pandemic responses.

Table 7 - Comparison of contribution analysis and realist evaluation

Method	How is it used?	Pros	Cons
Contribution analysis	<p>Used to understand the likelihood the intervention has contributed to an outcome observed through a step-by-step process which explores how the contribution would have come about, and uses a broad range of evidence to test this. This argues that a reasonable contribution causal claim can be made if:</p> <ul style="list-style-type: none"> ▪ There is a reasoned ToC for the intervention ▪ Activities of the intervention were implemented as per the ToC ▪ The ToC is supported and confirmed by evidence on observed results and underlying assumptions – the chain of expected results occurred. The ToC has not been disproved. <p>Other influencing factors have been assessed and <i>either</i> have been shown not to have made a significant contribution <i>or</i> their relative role in contributing to the desired result has been recognized.</p> <p>Findings are likely to be worded as ‘Analysis suggests that X, alongside the contributions of Y and Z, has made a meaningful contribution towards the achievement of outcome A’.</p>	<ul style="list-style-type: none"> ▪ Useful where there is scope or opportunity to affect rollout of a program ▪ Able to confirm or revise a ToC 	<ul style="list-style-type: none"> ▪ Quality of analysis and contribution claim dependent on the quality of the thinking on the attribution problem and ToC ▪ Does not provide definitive proof that the intervention has had a causal effect but rather provides an evidenced logical line of reasoning which gives some level of confidence of a contribution ▪ Works on average effects – therefore should not be used if there is a large degree of variance about how a program has been implemented or an expectation of different outcomes for different groups

³⁶ Ibid.

³⁷ Pawson, R. and Tilley, N. (1997). *Realistic Evaluation*. Sage.

Realist evaluation	<p>Used to understand ‘what works, for whom and in what circumstances’. Specific, hypothesized causal mechanisms, in context, are articulated (Context + Mechanism = Outcome) and evidence is gathered to test each. The method recognizes that context determines how, or if, this causal mechanism operates. It is particularly appropriate for evaluating:</p> <ul style="list-style-type: none"> ▪ new initiatives, pilot programs and trials, or programs that seem to work but ‘who for and how’ is not yet understood ▪ programs that will be scaled up, to understand how to adapt the intervention to new contexts ▪ programs that have previously demonstrated mixed patterns of outcomes, to understand how and why the differences occur. <p>Findings are likely to be worded as ‘remember A’, ‘beware of B’, ‘take care of C’, ‘D can result in both E and F’, ‘Gs and Hs are likely to interpret I quite differently’, ‘if you try J make sure that K has also been considered’.³⁸</p>	<ul style="list-style-type: none"> ▪ Refines public policy theory through the testing of underlying theories of how social systems work ▪ Provides a method to undertake impact evaluation when a counterfactual unfeasible ▪ Builds the wider evidence base of an area by providing a framework for testing hypotheses that may be relevant beyond a particular intervention ▪ Is method-blind, in the sense that it is an evaluation design that can employ a variety of analytical methods with it <ul style="list-style-type: none"> ▪ Is time-consuming and resource-intensive for both commissioner and contractor ▪ Requires subject-matter expertise to undertake ▪ Depending on the design of the evaluation, it may not provide an average net effect of the intervention
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3.4 Operationalizing the multi-stage evaluation

3.4.1 Scope of work

The evaluation is clearly focused on Gavi and the design, implementation and results of the COVAX Facility and COVAX AMC. As per the ToC (see Annex 8), the scope of work has been broken down into both *operational* (i.e. management structures and governance arrangements, risk management processes, and stakeholder engagement and communication functions) and *programmatic* (i.e. resource mobilization, market shaping,³⁹ procurement and delivery, equitable allocation and CRD) aspects of the COVAX Facility and COVAX AMC design.

While the evaluation should focus on Gavi and the COVAX Facility and COVAX AMC specifically, it is unlikely to be possible or helpful to evaluate these in isolation. Rather, the evaluation must consider the interconnectedness of roles, responsibilities and ways of working between implementing partners to facilitate COVAX Facility and COVAX AMC results. The evaluation will do this in two ways:

- It will not evaluate other COVAX implementing partners directly but will draw on the findings, conclusions and recommendations of other evaluation processes and evidence on the design, implementation and results of their work (i.e. CEPI’s role in development and manufacturing; WHO’s role in policy and allocation; and UNICEF’s and PAHO’s roles in procurement and delivery).⁴⁰ This will aid our understanding of how the ToC has played out in practice.⁴¹

³⁸ Realist Evaluation Learning Group. (2018, May 14). *Realist evaluation: is it worth it? Launching a new series reflecting on five years of realist evaluation practice at Itad*. Itad. <https://www.itad.com/article/realist-evaluation-is-it-worth-it-launching-a-new-series-reflecting-on-five-years-of-realist-evaluation-practice-at-itad/>

³⁹ We note that market shaping refers to the scope of activities intended and implemented by the COVAX Facility and COVAX AMC, which may not be as comprehensive as articulated in the Gavi Market Shaping Strategy.

⁴⁰ This will include the WHO ACT-A Strategic Review (already conducted); CEPI mid-term review and C-19 report (already conducted); Independent Commission for Aid Impact (ICAI) UK aid response to COVID-19 (already conducted); World Bank evaluation of COVID-19 response to save lives and protect the poor (2021); Foreign, Commonwealth and Development Office (FCDO) annual review of COVAX AMC (Q1 2022); International Development Association (IDA)/ Norwegian Agency for Development Cooperation (NORAD) evaluation of ACT-A/COVAX (Q3/4 2022); and evaluation of UNICEF contribution to ACT-A (2023). Johnson, L. and M. Gamarra (2021) COVID-19 Global Evaluation Coalition, “How are the COVID- 19 response and recovery efforts being evaluated? Landscape analysis of National and International evaluations and reviews of COVID-19 response and recovery efforts.” OECD, Paris, [www.covid19-evaluation-coalition.org/documents/COVID- 19_Landscaping_paper_Sept_2021](http://www.covid19-evaluation-coalition.org/documents/COVID-19_Landscaping_paper_Sept_2021).

⁴¹ Specifically, the intended completion of other (i.e. non-Gavi) implementing partner activities and achievement of results will be included as assumptions within the ToC for the COVAX Facility and COVAX AMC. Through the review of other evaluations and evidence on the design, implementation and results of their work these assumptions will be tested to gain an understanding of whether the ToC is working as intended.

- It will consider the ‘contribution’ of Gavi to areas that multiple COVAX partners jointly administer, particularly those areas that Gavi is not primarily responsible for (e.g. allocation, CRD support, procurement and delivery).

The evaluation should also consider the COVAX Facility and COVAX AMC in the context of COVAX and ACT-A more generally, and of the geopolitical and wider contextual factors at play. While not in scope for this evaluation to evaluate directly, this will include gaining a thorough understanding of:

- The geopolitical context of vaccine manufacturing and bilateral procurement
- Global and country-level pandemic preparedness and response strategies (self-financing participants (SFPs) and AMC)
- Bilateral and multilateral development bank support for vaccines and programming.

As such, this will necessarily involve taking into consideration factors both within and outside of Gavi’s direct control, and factors over which Gavi has both higher and lower levels of control and for which it can be held accountable.

3.4.2 Modules and methods

A multi-module design will provide an organizing framework and structure to the mixed-method approach. As stated above, no single method or approach will fully meet the evaluation needs; a mixed-method design is required. We propose four evaluation modules that provide a framework to organize the EQs and summarize the focus of the evaluation at different stages of the ToC. The modules enable a structured hybrid design whereby different methods can be employed for each module, according to where they are most fit for purpose. This is in line with best practice for complex and highly political initiatives, for which it is now widely argued that the best hope for ‘generating trustworthy causal inferences’ is through mixed methodology or multi-method evaluation designs.⁴²

In summary, our proposed modules, through a combination of methods, will cover the following:

- **Module 1 – Right things (design relevance and coherence):**⁴³ The evaluation will interrogate whether the COVAX Facility and COVAX AMC and its components were and remain relevant to the problems they were designed to address, by assessing: (1) whether the ToC/intervention design and revisions are appropriate and based on evidence and with clear assumptions; (2) what change in the pandemic or geopolitical context prompted design revisions; (3) whether and how stakeholders were involved in original design and subsequent revisions; (4) whether any design changes are needed for course correction; and (5) whether lessons can be learned for future pandemic responses.
- **Module 2 – Right ways (efficiency of implementation):** The need to differentiate between (i) cross-cutting EQs that focus on the operations of the COVAX Facility and COVAX AMC and (ii) EQs that focus on the programmatic areas across the ToC is important for this module. We make this explicit by dividing the ‘right way’ questions into two parts:
 - *Operational domain:* These EQs interrogate whether the COVAX Facility and COVAX AMC have been implemented successfully, by conducting an overall assessment of the extent to which the program has been implemented according to plans, with a specific focus on the extent to which (1) the COVAX Facility and COVAX AMC management structures and governance arrangements are fit for purpose, (2) risk management processes have been fit for purpose, (3) the costs of setting up and implementing the COVAX Facility and COVAX AMC were reasonable and appropriate, and (4) stakeholder engagement and communication has been appropriate.

⁴² Sanderson (2002). *Evaluation, Policy Learning and Evidence-Based Policy-Making*. Public Administration, 80, 1–22.

⁴³ The modules link with the OECD DAC criteria (<https://www.oecd.org/dac/evaluation/revised-evaluation-criteria-dec-2019.pdf>), with equity as a cross-cutting criterion. Sustainability is not explicitly referenced.

- *Programmatic domain*: This is focused on understanding if: resource mobilization, market shaping, procurement and delivery, equitable allocation and CRD inputs, activities and outputs have been implemented successfully and as intended.
- **Module 3 – Right results (effectiveness and impact)**: The evaluation will seek to understand the available evidence on the achievement of outcomes and goals (intended and unintended), the contribution of the COVAX Facility and COVAX AMC to these results, and the barriers and enablers to their achievement.
- **Module 4 – Learning**: Summarizing and prioritizing lessons learned, building on the work done under the earlier modules (to inform immediate course correction) and on what can be learned from other agencies, arrangements and contexts and applied for the achievement of intended outcomes and impact. This will include opportunities for transformative learning, for instance on the overall design of the COVAX Facility and AMC and the contextual constraints which influence this design, and implications for future pandemic preparedness.

Having constructed an ‘evaluation’ ToC,⁴⁴ the principal methods for the evaluation will be as follows:

- **Political economy analysis** will be used to identify the political and practical dimensions of designing and operationalizing a global vaccine procurement and delivery mechanism, and to analyze the appropriateness of the selected design within the context of the incentives, relationships, and distribution and contestation of power between the different stakeholders engaged and with interests in its design and operationalization.
- **Benchmarking** will be used in a variety of ways across the scope of work, including to benchmark design decisions against criteria to assess the appropriateness of decision making, and to establish if the right systems, processes and capacities were/are in place through comparison to established norms, standards, best practices and comparator organizations.
- **Process tracing** will be used to assess whether intended actions and activities have been implemented as intended, and the linkages and assumptions underpinning the ToC have worked as intended, and – where this is not the case – explore how and why so. This will include analysis of alternate explanations for observed results, and of unintended consequences and barriers and enablers to the achievement of results.
- **Root cause analysis** will be used to analyze the underlying causes of observed issues or challenges during implementation, where the root causes are not well understood.
- **Contribution analysis** will, building on findings from other methods, be used to understand how and why the COVAX Facility and COVAX AMC has contributed to observed outcomes.

Annex 10 presents a detailed evaluation framework for the multi-stage evaluation, including proposed methods and data sources (documentation, information sources, KIIs, focus group discussions, web-surveys, comparator case studies and country case studies) for each EQ. Annex 12 describes the analytical methods proposed and how they will be used in more detail.

3.4.3 Synthesis

Framing the overall multi-stage evaluation within a theory-based approach will support cross-EQ synthesis and enable the formulation of strong responses to high-level EQs, overall conclusions and recommendations. For analysis against individual EQs it will be important to draw together evidence from different data sources. This will be coded and used to populate standardized evidence matrices. This structured way of working and approach enables a systematic approach to collating, analyzing, summarizing and comparing data and findings against different elements of the ToC and for the EQs. This

⁴⁴ This will include: nested ToCs that focus on specific programme components; analysis of the supporting evidence base and assumptions; and a timeline of design iterations since launch. It will be revised and updated frequently throughout the evaluation process.

standardized approach also ensures that users of the final report are able to trace back from recommendations to specific findings and the data upon which they are based. It also enables a comprehensive and systematic approach to cross-EQ synthesis, which will be critical to developing well-rounded and robust findings against the high-level EQs, and in development of the overall conclusions on strengths and weaknesses, and recommendations on design, implementation and results. It is recommended that synthesis be conducted using a thematic analysis approach, or a variation with similar attributes. This involves systematically identifying significant, reoccurring or common patterns/themes and summarizing them under thematic headings. Themes are then related to each other and grouped into larger overarching categories.^{45,46}

We expect synthesis to take place regularly and at multiple levels, including:

- *Country case study level:* Analysis of data and synthesis of findings at individual country case study level and across country case studies
- *By module:* Analysis of data against individual EQs synthesized through the lenses of right things, right way, right results and learning
- *By programmatic area:* Analysis of data synthesized through the lenses of resource mobilization, market shaping, procurement and delivery, equitable allocation and CRD
- *Cross-module:* Analysis of data synthesized to identify overall strengths and weaknesses
- *For equity:* Synthesis to understand how equity has been considered in both the design of the COVAX Facility and COVAX AMC (equity in process) and results achieved (equity in outcomes) (see Table 5).

The synthesis process should involve a series of steps to ensure a systematic, rigorous qualitative analysis, as set out in Annex 12.

It will be important to work alongside the Office of the COVAX Facility to co-create conclusions and recommendations. These processes work best where stakeholders have seen draft findings in advance and have had an opportunity to provide initial comments. Allowing this before the workshop will help to ensure that stakeholders provide a more reflective perspective, which, based on our experience, generates a more conducive environment for thinking through overall conclusions and recommendations on how best to move forward. For the avoidance of doubt, while the co-creation process should help to build consensus on conclusions and recommendations, these should remain the responsibility of the independent evaluators, who must be free to reject suggestions of others if it is felt appropriate to do so.

3.4.4 Phasing of evaluation activity

Evaluation activity should be phased to ensure that outputs are relevant and useful and meet the overall evaluation purpose. As above, baseline, midterm and end-term formative-summative evaluations should cover the full scope of work (i.e. EQs across all four modules, including all cross-cutting programmatic modules)⁴⁷ and be designed to meet an accountability and learning objective. These evaluation processes should be tailored – through stage-specific EQs – to ensure that the evaluation is answering relevant questions and is focused on those questions that are possible to answer at any given moment in time. For example, questions about design will be a high priority at the baseline; however, questions on impact cannot generally be answered at this stage as there is a series of activity, output and uptake processes to go through to get to impact.

⁴⁵ Gale, N. K., Heath, G., Cameron, E. et al. (2013). *Using the framework method for the analysis of qualitative data in multi-disciplinary health research*. *BMC Med Res Methodol* 13, 117. <https://doi.org/10.1186/1471-2288-13-117>

⁴⁶ Braun, V. and Clarke, V. (2006). *Using thematic analysis in psychology*. *Qualitative Research in Psychology*, 3:2, 77–101. DOI: 10.1191/1478088706qp063oa.

⁴⁷ I.e. resource mobilization, market shaping, procurement and delivery, equitable allocation and CRD.

As shown in Table 8, we divide the evaluation life span into three phases and consider the relative emphasis on the scope of work across each phase. Each formative-summative evaluation would be interspersed with 'rapid reviews' focused on specific parts of the ToC where learning is required (e.g. to address operational issues and influence rapid course correction). Annex 14 illustrates how rapid reviews complement and add value to the overall formative-summative evaluations and continuous learning function led by the Office of the COVAX Facility/Gavi ELU.

Stage-specific EQs and rapid review topics will be aligned to Secretariat learning needs and will provide useful evidence, findings and recommendations to inform course correction and efforts to strengthen future pandemic preparedness.

The formative review and baseline study, midterm reviews and end-term evaluation would be timed to ensure that findings, conclusions and recommendations are made available at least two months prior to either the April/May or October PPC meeting, ensuring that evaluation outputs are also available to inform the subsequent May/June and November Board meetings each year. This would mean conducting an indicative six-month evaluation process between either August and January or February and July. The exact timing and scope of work, as determined by stage-specific EQs, should be agreed separately for each evaluation process, in part based on the expected content of each PPC/Board meeting it is being timed to coincide with and inform.

We provide a summary of the primary users for each of the EQs in Annex 10 (Table 20) and an overview of when different types of evaluation findings (i.e. findings on course correction versus future pandemic preparedness) are likely to be produced, to meet different evaluation user needs anticipated, in Annex 16 (Table 25).

The flexibility to conduct rapid reviews when evidence is needed will improve the chances that learning comes at the right time to inform course correction in a highly dynamic environment.

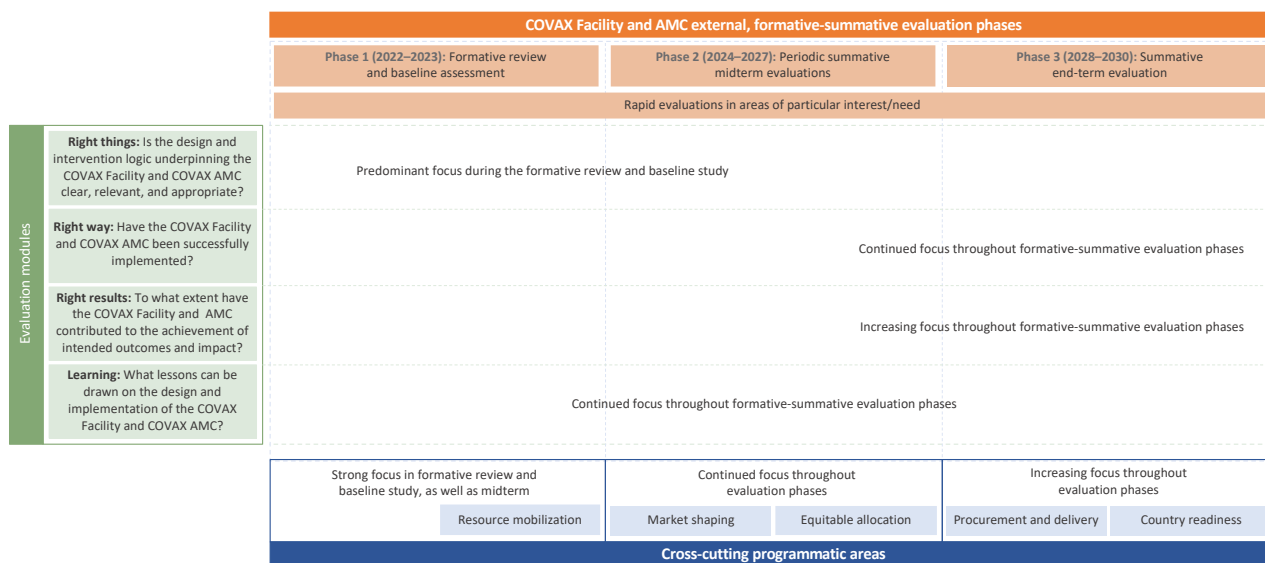
Table 8 - Overall staged arrangement of evaluation activity

Stage and type of evaluation activity	When
Phase 1: Formative review and baseline study: Learning-focused formative review of design and set-up to highlight what has worked well and less well. Central focus on Module 1 and Module 2. Reduced focus on Module 3.	2022 to 2023
Phase 2: Midterm review(s): Conducted periodically (e.g. annually or biannually) from the formative review and baseline study through to end-term evaluation. Scope would shift from formative/process evaluations focused on Module 1 and Module 2 in earlier years to place more weight on summative evaluations focused on Module 3 over time.	2024 to 2027
Phase 3: End-term: Summative evaluation covering full scope but focused primarily on Module 3.	2028 to 2030
Rapid reviews: Conducted in targeted technical/thematic areas as needed, but outside of other evaluation work listed above.	Throughout

Figure 2 presents the envisaged areas of focus within the evaluation scope and how this will evolve over time and at different phases of the evaluation. This includes:

- **Phases:** As shown in orange, the 10-year evaluation lifespan is split into three phases covering the need for periodic baseline, midterm and end-term evaluation exercises. Rapid reviews would be conducted flexibly across those phases, alongside continuous learning led by the Gavi ELU.
- **Modules:** The four modules and high-level questions for each are presented in green on the left-hand side with the green arrows running from left to right indicating the relative emphasis placed on each across the evaluation phases.
- **Programmatic areas:** The five programmatic areas identified in the ToC are presented in blue. Each of the areas will be considered at each phase but at different levels of intensity, as indicated by the diagonal arrows. This is dictated by the information that is available and what is most useful to be answered at a given moment in time.

Figure 2 – Multi-stage evaluation plan



* Subject to change and/or refinement based on the trajectory of COVAX Facility and longevity of COVAX AMC

3.5 Risks, challenges and limitations

The evaluability assessment has raised a number of potential risks, challenges and limitations to conducting the multi-stage evaluation, as set out in Table 9 alongside proposed mitigation strategies. Specific recommendations are also included, which are summarized/repeated in Section 4.3.

Table 9 - Risks, challenges and limitations

Risk, challenge, limitation	Mitigating measure(s)
<p>The evaluation scope of work does not meet all stakeholder needs, particularly with respect to the global health community’s desire for holistic reporting on the extent to which COVAX has been able to (i) address power imbalances to ensure equitable access to COVID-19 vaccines and (ii) support efforts that inform future pandemic preparedness efforts.</p>	<p>Significant efforts have been made during the evaluability assessment phase to elicit a broad range of views on the evaluation purpose and scope, which have informed the proposed evaluation design and the communications and learning plan. The distinction between (i) holistic formative-summative evaluation processes conducted every one to two years, interspersed with rapid reviews in select areas to inform learning, and (ii) the continuous learning function provided by the ELU, conducted alongside these, is designed to best meet all stakeholder needs.</p> <p>With respect to the specific request referenced, fully answering this question would require a broader remit than this evaluation’s focus on just the COVAX Facility and COVAX AMC. We propose to mitigate this risk to the extent possible through this evaluation with methods such as political economy analysis, to explore how power imbalances and political and economic concerns and incentives have influenced (a) design and implementation decisions in the COVAX Facility and COVAX AMC, and (b) SFP and AMC countries’ decision-making processes around whether and how to engage with the COVAX Facility and COVAX AMC.</p> <p>It is, however, recommended that Gavi work with other COVAX implementing partners to integrate/align this evaluation process with others conducted on similar topics and other areas of COVAX to learn lessons more holistically.</p>
<p>Fatigue within the Office of the COVAX Facility and other COVAX implementing partners, and limited bandwidth to engage with the evaluation, may reduce ability to obtain all of the</p>	<p>While country stakeholders and the staff of COVAX implementing partners are extremely busy and will have limited time to engage with the evaluation, the evaluability assessment process did indicate strong interest and willingness to do so. Nonetheless, a number of steps are included within the proposed approach to mitigate this risk:</p> <ul style="list-style-type: none"> The proposed evaluation design is based around an approach that is robust but practical to implement. The selection of evaluation methods has been made in part based on the availability of stakeholders to engage in the evaluation process.

<p>most relevant data sources and solicit sufficient evidence to robustly answer EQs.</p>	<ul style="list-style-type: none"> • The expectations for stakeholder engagement for each evaluation exercise are clearly presented in this report, alongside the implications of this level of engagement not being met. • Efforts will be made to reduce the evaluation footprint, such as by minimizing the number of requests of each stakeholder, holding focus group discussions where feasible, and making use of web-surveys and remote working (including for interviews and learning events) where possible. • Agreement on the timing of each evaluation exercise will be based, in part, on stakeholder availability. • Sufficient time to collect data will be built into the workplan for each evaluation exercise, designed to give greater flexibility to stakeholders on when to provide their inputs.
<p>It is recommended that the Gavi ELU support the implementation of these steps and continue its role in stimulating interest and engagement of stakeholders in the evaluation.</p>	
<p>Limited involvement of broader stakeholder groups (i.e. beyond the core partners directly engaged in implementing COVAX) in data collection may affect perceived or actual objectivity and independence of evaluation findings.</p>	<p>Ensure engagement with a broad set of stakeholder groups/constituencies representing the key bodies and working structures involved in the governance, management and implementation of COVAX, and specifically the COVAX Facility and COVAX AMC. Of particular importance is the need to engage with a broad range of representatives from the Global South, and specifically AMC92 country representatives and civil society representatives, as well as key partners (e.g. AVAT, PAHO, UNICEF and WHO).</p> <p>Steps are also proposed to ensure that the evaluation has good governance and oversight itself, including with:</p> <ul style="list-style-type: none"> • An owner within Gavi, anticipated to continue to be from the ELU, working in strong collaboration with the Office of the COVAX Facility. • A steering and technical advisory group internal to the evaluation team to guide the evaluation and to act as a broker, as needed, with external stakeholders. • An evaluation team with strong internal capacity to implement the evaluation, a robust methodology and workplan in place, access to required data, and strong quality assurance function, led by a senior evaluation expert, to ensure that the evaluation is implemented as intended and in adherence to best practice and ethical guidelines. • An advisory panel to the Gavi Secretariat to advise on quality, fitness for purpose, and risk. We note that the Evaluation Steering Committee and Evaluation Advisory Committee jointly meet this need.
<p>It is recommended that the Gavi ELU support the implementation of these steps to ensure broad stakeholder engagement in the evaluation and good governance.</p>	
<p>Different perspectives and understandings of the intervention logic may make it difficult to develop a single ToC that is universally accepted, thus reducing buy-in among some stakeholders.</p>	<p>Our approach to evolving the ToC has involved: (a) eliciting various stakeholders' existing conceptions of how the COVAX Facility and COVAX AMC is expected to work; and (b) constructing a single model that is evaluable but seeks to represent the diversity of stakeholder perceptions elicited. We have not yet conducted the planned participatory exercise to systematically explore and build consensus around the ToC for the evaluation. This workshop should take place at the outset of the proposed formative review and baseline study with this purpose in mind and to ensure that the ToC is sufficiently well developed to be evaluable. It is recommended that the Gavi ELU support the facilitation of this workshop.</p>
<p>Stakeholder views and perspectives may be influenced by the high level of commentary on COVAX in the media and academic and gray literature.</p>	<p>While we cannot guarantee that stakeholder inputs are not influenced by the media, political context and commentary surrounding COVAX, steps are proposed to mitigate the risk that the data collected by the evaluation (and subsequent findings, conclusions and recommendations) might reflect such stakeholder bias. The steps are as follows:</p> <ul style="list-style-type: none"> • Robust selection of a cross-section of stakeholders to be interviewed, including the broad set of stakeholder groups/constituencies involved in the governance, management and implementation of the COVAX Facility and COVAX AMC. Of particular importance is the need to engage with a broad range of representatives from the Global South, and specifically AMC92 country representatives and civil society representatives, as well as key partners (e.g. AVAT, PAHO, UNICEF and WHO). This will enable us to speak to informed experts able to assert their own independent viewpoints and different world viewpoints – cutting through the media discourse and commentary, to help us form independent and well-rounded judgments.

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- Ensuring the positionality of the respondent is recorded (beyond job title and organization), as this will help at analysis stage to separate out and triangulate different findings from different stakeholder groups.
 - Robust triangulation with other evidence, and how this has been established and evolved over time, and building in of flexibility to pursue emerging or unexpected lines of enquiry.
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The evolving nature of the pandemic and the intervention logic for the COVAX Facility and COVAX AMC may limit the applicability of EQs, findings, conclusions and recommendations.

Through the ToC development process we will seek to capture the evolution of the intervention logic over time. Recognizing the responsiveness of the COVAX Facility and COVAX AMC design to an evolving context, each stage of the evaluation will start with an update of any revisions of design and strategy since the last assessment. The ToC will be updated as needed. Every stage of the evaluation will include a ToC situation assessment and assess the relevance, coherence and appropriateness of design choices, including the decision-making process as well as the content of any design revisions.

This response will be appropriate for most changes to the intervention logic. However, it may not cover all eventualities (e.g. where COVAX was ceased midterm or where the design was changed so much that prior evaluation efforts became redundant). In such a situation, the evaluation scope of work and design would need to be immediately revised.

We have proposed periodic evaluation processes with stage-specific questions at each juncture, interspersed with rapid reviews on specific issues of interest. We have also proposed an approach and methods that major on understanding the importance of context to implementation and results. This will allow the evaluation to ensure it is asking relevant questions and take account of the evolving context at any given moment in time. We also note that, while the evaluation design has been highly dynamic in its first two years of operations, we could also reasonably expect it to reach more of a steady state in years to come.

A number of aspects of the evaluation may be highly sensitive and possibly contentious, for instance in relation to the proposed political economy analysis when seeking to understand the incentives, relationships, and distribution and contestation of power between the different stakeholders engaged in the design and operationalization of the COVAX Facility and COVAX AMC. This may result in some stakeholders seeking to discredit the evaluation findings in order to avoid addressing the issue(s).

We recognize the timeliness of this independent evaluation and the high stakes involved, and have set out an approach to deliver robust, evidence-based insights in response to the EQs and to meet the evaluation purpose. Conducting evaluative work can involve delivering difficult messages on things that may not be working as well as they should, or that could be done differently. We are mindful of the intensity and level of effort the COVAX implementing partners have invested in establishing the COVAX Facility and COVAX AMC and delivering results, and in response our communication will always be clear, constructive and appreciative, but we will not shy away from being critical where we feel it is needed. We will work hard to build relationships with key stakeholders to facilitate constructive exchanges, ensuring that what we say is always grounded in sufficiently robust evidence. This will include engaging with our Technical Advisory Group to ensure that messaging is tailored appropriately and, where needed, comes from the right people.

It is further recommended that the Gavi ELU ensure that the steps proposed to ensure good governance for the evaluation are fully adopted to further reduce the risk that the evaluation findings are unfairly criticized or discredited.

Some causal pathways in the ToC are not able to be fully explored and understood due to a lack of data and evidence on the completion of non-Gavi COVAX implementing partner activities and results. This may mean that only partial responses to EQs can be provided.

As per Section 3.4.1 on the scope of work, the evaluation will not evaluate other COVAX implementing partners but will consider the interconnectedness of roles, responsibilities and ways of working between implementing partners to facilitate COVAX Facility and COVAX AMC results. It will do this in two ways:

- It will draw on the findings, conclusions and recommendations of other evaluation processes and evidence on the design, implementation and results of their work (i.e. CEPI's role in development and manufacturing; WHO's role in policy and allocation; and UNICEF's and PAHO's roles in procurement and delivery). This will aid an understanding of how the ToC has played out in practice.
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- It will consider the 'contribution' of Gavi to areas that multiple COVAX partners jointly administer, particularly those areas that Gavi is not primarily responsible for (e.g. allocation, CRD support, procurement and delivery).

It is recommended that the Gavi ELU maintain contact with COVAX implementing partners and other groups (e.g. the OECD COVID-19 Global Evaluation Coalition) to keep abreast of other evaluation processes and gain access to documents as soon as possible.

3.6 Evaluation governance

An evaluation of this scale, duration and multi-module design, and with such significant stakeholder interest, requires good oversight itself. Assuming an outsourced evaluation team, it is considered that the evaluation needs three elements of governance:

- An owner within Gavi, anticipated to continue to be from the ELU, working in strong collaboration with the Office of the COVAX Facility
- A steering and technical advisory group internal to the evaluation team to guide the evaluation and to act as a broker, as needed, with external stakeholders
- An evaluation team with strong internal capacity to implement the evaluation, a robust methodology and workplan in place, access to required data, and strong quality assurance function, led by a senior evaluation expert, to ensure that the evaluation is implemented as intended and in adherence to best practice and ethical guidelines
- An advisory panel to the Gavi Secretariat to advise on quality, fitness for purpose, and risk. We note that the Evaluation Steering Committee and Evaluation Advisory Committee jointly meet this need.

4. Evaluation activities for Phase 1 (2022–23)

This section describes the evaluation and learning activities proposed for Phase 1 of the multi-stage evaluation covering the period 2022–23. The main activities are (1) a formative review and baseline study; (2) rapid reviews in particular areas of interest/need; and (3) support for a continuous, real-time learning function.

The focus of this phase is a combination of (i) accountability for intermediate results and (ii) learning for course correction. Future stages from 2024 onwards will have an expanded focus to include accountability for outcome-level results and generating transformative learning for future pandemic responses.

4.1 Formative review and baseline study design

Building on the sections above and the expectations and priorities articulated by stakeholders through this phase of work, this section sets out the scope of work and our proposed approach to the formative review and baseline study. This will result in an overall evaluation report due in 2022 (timing to be confirmed).

4.1.1 Purpose and scope of the formative review and baseline study

The RfP asked for three related pieces of work: an evaluability assessment; an evaluation design; and a baseline study. A baseline study would usually seek to collect data at the outset of a project or program, against which progress can be measured over time. However, given that COVAX was established in mid-2020 and the ‘baseline’ study will be conducted in 2022, Itad’s proposal and inception report have framed the study as a review of what has worked well and less well to date in designing and operationalizing the COVAX Facility and COVAX AMC, and as an opportunity to test the early stages of the ToC and take a snapshot of progress against critical areas of the ToC at this point in time.

Given the utility and stakeholder demand for a review of this type, such an approach is still considered to be most relevant in order to meet both an overall accountability and learning purpose, and could also be used to collect baseline data essential for measurement of progress over time on the effectiveness and performance of the COVAX Facility and COVAX AMC.

To avoid any confusion on the scope of this study, it is referred to in this report as a ‘formative review and baseline study’. The approach set out below is aligned to the overall methodological approach for the multi-stage evaluation set out in Section 1. Annex 11 presents a detailed evaluation framework, including stage-specific EQs for each phase of evaluation, and proposed methods for each EQ which are elaborated in Annex 12.


4.1.2 EQs for the formative review and baseline study

The stage-specific EQs and the key issues for consideration for the formative review and baseline study are shown in Table 10. The fact that there is a relatively large number of key issues is intentional, as we are aiming to ensure that there is comprehensive coverage of the crucial initial stages of the COVAX Facility and COVAX AMC.

Table 10 - Formative review and baseline study EQs

Module & EQ	Stage-specific questions for formative review and baseline study	Key issues for consideration during the formative review and baseline study	
 1. Right things: Design	1	Given the uncertain nature of the emerging pandemic, was the COVAX Facility and AMC design developed in an evidence-based and coherent manner to maximize the chances for success?	<ul style="list-style-type: none"> Design choices to be a global purchasing and allocation mechanism (including SFPs) Market shaping strategies employed Design of AMC Operationalizing the allocation mechanism based on principles of equity and fairness Relative balance between focus on scaling vaccine procurement and scaling country-level delivery
	1.1	To what extent is the overall design of the COVAX Facility and AMC and specific strategies clearly justified and documented, including the evidence base, and assumptions related to causal links between outcomes? Is the overall design clear and coherent?	<ul style="list-style-type: none"> ToC and intervention logic evidence base and assumptions Problem/context analysis, recognizing dynamic market, geopolitical and epidemiological context Alignment to COVAX vaccine pillar and ACT-A Roles, responsibilities and ways of working between organizations Other strategic options and trade-offs considered and documented
	1.2	How has the design shifted over time based on the evolving pandemic and geopolitical context, and based on what justification and evidence?	<ul style="list-style-type: none"> Articulation of prevailing context Mapping of adaptation and modification to ToC, and justification provided, including evidence and assumptions Other strategic options and trade-offs considered and documented
	1.3	How were external stakeholders and COVAX partners contribute to the original design of the COVAX Facility and AMC, and what impact did this have?	<ul style="list-style-type: none"> Mapping of key stakeholders by programmatic area Understanding of power asymmetries between stakeholders Identification of opportunity for meaningful engagement by different constituency groups
	1.4	Are design revisions needed to inform course correction to facilitate short-term progress and results?	<ul style="list-style-type: none"> Alternative strategic options and trade-offs 'Path dependencies' for design revisions to be successful
 2. Right way: Implementation	2	Have the COVAX Facility and AMC been successfully set up and implemented thus far?	<ul style="list-style-type: none"> Synthesis of operational and programmatic issues analyzed through sub-questions below
	2.1	Are COVAX Facility and AMC operations suitable and appropriate, and been successfully set up and implemented thus far?	<ul style="list-style-type: none"> Synthesis of operational issues analyzed through sub-questions below
	2.1.1	Are the COVAX Facility and AMC management structures and governance arrangements suitable and appropriate for a new entity working in an emergency setting?	<ul style="list-style-type: none"> Evolution of management/governance structures Supportiveness of management and governance arrangements in operationalizing the COVAX Facility and COVAX AMC
	2.1.2	Are risk management systems, processes and capacities suitable and appropriate for dealing with the inherent risks associated with the COVAX Facility and AMC mandate?	<ul style="list-style-type: none"> Risk assumed on behalf of the group of organizations that constitute COVAX, and challenges posed, if any Identification and mitigation of financial and programmatic challenges and risks
	2.1.3	Were the initial set-up costs for the COVAX Facility and AMC reasonable and appropriate for the organization mandate and proposed scale of operations?	<ul style="list-style-type: none"> Review of costs incurred by Gavi in set up of COVAX Facility and AMC Level of Gavi staff effort in managing Office of the COVAX Facility Staff availability and working conditions
	2.1.4	How were external stakeholders and COVAX partners engaged in the early implementation of the COVAX Facility and AMC, and how did this guide decision making to support governance, management and implementation?	<ul style="list-style-type: none"> Presence of appropriate stakeholder engagement plan Implementation of stakeholder engagement plan Implementation of processes to ensure coherence and coordination across partners working to achieve common outcomes (e.g. within the COVAX pillar, other ACT-A pillars, Health Systems and Response Connector (HSRC), International Financial Institutions (IFIs) and regional organizations and mechanisms, i.e. AVAT)
	2.2	Have COVAX Facility and AMC programmatic areas been successfully set up and implemented thus far?	<ul style="list-style-type: none"> Synthesis of programmatic issues analyzed through sub-questions below For all sub-questions, consideration of the respective roles and contributions of all COVAX implementing partners to implementation

	2.2.1	Was a persuasive and appropriate resource mobilization strategy articulated to secure adequate resources for full and timely implementation of intended activities? To what extent were initial expectations and targets met in a timely manner?	<ul style="list-style-type: none"> ▪ Presence of investment case ▪ Use of innovative financing mechanisms ▪ Sufficiency of resources mobilized to allow for the ToC to be operationalized as intended and in a timely manner ▪ Evolution of strategy in response to context (e.g. collaboration with World Bank, incorporating donations, cost-sharing for procurement and in-country delivery, and the emergence of new procurement platforms, such as AVAT)
	2.2.2	Was the market shaping approach adopted sufficiently powered and implemented to meet initial expectations on vaccine manufacturing and pricing, and to secure supply?	<ul style="list-style-type: none"> ▪ Presence of systems, processes, capacities and tools to deliver market shaping objectives ▪ Contextual barriers or enablers to the involvement and influence of the COVAX Facility and AMC in market shaping ▪ Strengths and weaknesses of APAs to achieve the desired outcomes given the changing landscape ▪ Trade-offs between the range of market objectives ▪ Coordination/communication with participants ▪ Implementation course corrections required
	2.2.3	Was the role of the COVAX Facility and AMC clearly articulated, agreed and implemented to support procurement and delivery functions? How well has this worked to date?	<ul style="list-style-type: none"> ▪ Clarity of roles and responsibilities for the COVAX Facility and AMC ▪ Approaches used to coordinate with other partners ▪ Evolution of procurement and delivery processes to respond to the changing context and needs (e.g. managing donations, humanitarian buffer, SFPs) ▪ Processes to coordinate between securing advance purchase agreements (APAs) and the later stages of procurement and delivery of doses
	2.2.4	To what extent has the allocation mechanism design been reviewed, adjusted, and operationalized? Does this appear likely to ensure a fair and equitable distribution of COVID-19 vaccines?	<ul style="list-style-type: none"> ▪ Stakeholder engagement ▪ Coordination with partners to operationalize the allocation approach ▪ Distribution of volumes consistent with the allocation mechanism ▪ Alignment of vaccine distribution to country needs and preferences (e.g. presentation, expiry date) ▪ Alternative options and trade-offs
	2.2.5	Was the role of Gavi and the COVAX Facility and AMC vis-à-vis CRD clearly articulated, agreed and implemented in a timely manner?	<ul style="list-style-type: none"> ▪ Prioritization of CRD vis-à-vis other programmatic areas over time ▪ Presence of systems, processes and capacities to assess and support CRD, including country readiness assessments ▪ Coordination with other stakeholders for achievement of joint results ▪ Country communications on vaccine availability and allocation decisions ▪ Alignment of technical assistance (TA) and sufficiency of resource envelope to country needs for delivery readiness ▪ Presence of feedback loops to identify and address lessons learned and adapt ways of working ▪ Timeliness of disbursements
 3. Right results: Outcomes and impact	3	What initial COVAX Facility and AMC results have been achieved and to what extent are intended outcomes and impacts on track to being achieved?	<ul style="list-style-type: none"> ▪ Synthesis of issues analyzed through sub-questions below ▪ Analysis of global geopolitical and economic landscape of actors involved in the delivery of COVID-19 vaccines
	3.1	To what extent does the early emerging evidence suggest that intended intermediate outcomes across the programmatic areas of the ToC are likely to be achieved?	<ul style="list-style-type: none"> ▪ Verification and triangulation of Monitoring and Reporting Framework data on intermediate outcomes across the programmatic areas of the ToC (i.e. market shaping, procurement and delivery, equitable allocation and CRD)
	3.2	To what extent does the early emerging evidence suggest that intended outcomes and goals are likely to be achieved?	<ul style="list-style-type: none"> ▪ Verification and triangulation of Monitoring and Reporting Framework data on outcomes and goals, including (1) delivery to countries, (2) number of persons vaccinated, (3) equitable access

	3.3	What emerging evidence is there to suggest unintended consequences and results beyond the ToC?	<ul style="list-style-type: none"> ▪ Effects of the COVAX Facility and AMC on routine immunization efforts ▪ Other unintended results areas
	3.4	To what extent does the early emerging evidence suggest that the COVAX Facility and AMC is likely to contribute to achievement of outcomes and impacts within the global geopolitical and economic landscape?	<ul style="list-style-type: none"> ▪ Consideration of the role of Gavi and Office of the COVAX Facility vis-à-vis other COVAX implementing partners and stakeholders working for the achievement of common outcomes and impact
	3.5	What does the early emerging evidence suggest are barriers and enablers to achieving results?	<ul style="list-style-type: none"> ▪ Review and synthesis of barriers and enablers identified through literature and in conducting the formative review and baseline study
	4	What are the emerging lessons from the design and implementation of the COVAX Facility and COVAX AMC that have implications for course correction and Gavi 5.0?	<ul style="list-style-type: none"> ▪ Synthesis and prioritization of lessons learned
 <p>4. Learning</p>	4.1	What are the emerging lessons from the design and implementation of the COVAX Facility and COVAX AMC that have implications for course correction?	<ul style="list-style-type: none"> ▪ Specific areas for learning are posed in Section 4.1.6 and Annex 10
	4.2	What are the emerging lessons from the design and implementation of the COVAX Facility and COVAX AMC that have implications for Gavi 5.0?	<ul style="list-style-type: none"> ▪ Specific areas for learning are posed in Section 4.1.6 and Annex 10
	4.3	What are the emerging lessons from the design and implementation of the COVAX Facility and COVAX AMC that have implications for future pandemic preparedness?	<ul style="list-style-type: none"> ▪ N/A for formative review and baseline study
	4.4	Which agencies, arrangements and contexts are most likely to provide useful learning for different aspects (design, operational, programmatic) of the COVAX Facility and COVAX AMC, and what can we learn from them?	<ul style="list-style-type: none"> ▪ Review and synthesis of learning generated from comparator analyses conducted across formative review and baseline study
	4.5	What can be learned from a comparison of countries' experiences of securing maximum possible vaccination supply, and applied to the COVAX Facility and/or COVAX AMC for the achievement of outcomes and impact?	<ul style="list-style-type: none"> ▪ Identification of outliers from cross-country portfolio analysis ▪ Analysis of underlying reasons for observed differences, including how countries across the income spectrum have responded to the realities of sourcing vaccines differently, and which agencies and/or arrangements each has drawn down on, or not, and why

4.1.3 Methodology for the formative review and baseline study

In line with the overall methodological approach set out in Section 3.4.2, the methods proposed for the formative review and baseline study are set out below by evaluation module. This is supplemented by a detailed evaluation framework in Annex 11 and a description of analytical methods in Annex 12.

4.1.3.1 Module 1: Right things

The formative review and baseline study will seek to fully understand the COVAX Facility and AMC design and how it has evolved over time to analyze and assess its appropriateness within the prevailing global, regional and country context and the geopolitical and wider contextual factors at play. This will respond to EQs 1–1.4. It will involve:

Constructing a revised ‘evaluation’ ToC for the COVAX Facility and AMC

A first step is to construct and document a ToC for the COVAX Facility and AMC that is agreed by relevant stakeholders, taking into account that the design has evolved since its launch in April 2020, with discussions underway for further revisions in 2022 and beyond. The output will be a ToC for the COVAX Facility and COVAX AMC as of 2022, including nested ToCs that focus on specific program components.⁴⁸ In line with the overall approach, this will involve framing ToC assumptions and attention to causal mechanisms. Another output is a timeline of design iterations since launch. These outputs will serve as an analytical framework for other aspects of the evaluation, including design (relevance & appropriateness), implementation and results.

The process for constructing the ToC will be participatory, based on the principle of joint reflection by relevant stakeholders involved in strategy development since launch, including global, regional and country stakeholders. Sampling of key informants for Module 1 will seek to balance interests and perspectives to ensure comprehensive, balanced evidence. Recognizing the competing commitments of key staff from Gavi and COVAX partners, the participatory process will be iterative and creative. A first step is to undertake KIIs and further documentation review to clarify design considerations and choices made during the life of the COVAX Facility and COVAX AMC, including trade-offs. Annex 8 contains the ToC constructed as part of the evaluability assessment for the COVAX Facility and COVAX AMC, which will serve as a starting point for discussion. One or more feedback workshops will enable a facilitated dialogue among various stakeholders involved in design decisions, highlighting consensus and/or varying perspectives on design trade-offs.

Political economy analysis and benchmarking of design decisions

These methods will be used in a complementary way to evaluate the appropriateness of the COVAX Facility and AMC design. Evidence is drawn from KIIs, focus group discussions (including ToC consensus workshops), a desk review and a web-based stakeholder survey.⁴⁹

Using the design timeline mentioned above, we will identify the political and practical dimensions of designing and operationalizing a global vaccine procurement and delivery mechanism, and analyze the appropriateness of the selected design within the context of the incentives, relationships, and distribution and contestation of power between the different stakeholders engaged and with interests in its design and operationalization. As per Section 2.1, evaluating the appropriateness of overall design and specific program strategies will explore the counterfactual (‘what if’) scenarios of various strategic options considered and not considered, or comparative analysis of similar interventions and strategies (comparators).

⁴⁸ For example, Annex 8 provides a draft nested ToC for the market shaping programmatic area. This will be refined and further developed in the initial stages of the baseline study and will serve to help frame the baseline evaluative study on the market shaping element of the programme.

⁴⁹ Stakeholder survey across all modules; will include relevant (open-ended) questions on relevance and design.

We will use benchmarking to assess the process of decision revisions against a set of criteria around reasonableness,⁵⁰ fairness,⁵¹ equity and responsiveness, on the basis of a literature review and validated through KIIs.

We will use various established sectoral political economy analysis (PEA) methodologies⁵² for description, analysis and mapping of the political economy around access to COVID-19 vaccines, to assess stakeholder influence against alignment with COVAX principles, aims and strategies (e.g. global vaccine manufacturing and allocation).

4.1.3.2 Module 2: Right way

The formative review and baseline study will provide a formative, learning-focused assessment of implementation progress for each of the programmatic areas of the ToC (resource mobilization, market shaping, procurement and delivery, equitable allocation and CRD) and to understand how well each of the operational aspects of the ToC (including the management and governance model, stakeholder engagement and communication, and risk management systems and processes) have facilitated this progress. This will involve the following:

Benchmarking against objective criteria and comparator analysis

A benchmark – what ‘good’ looked like – will be established through the use of best practice frameworks, norms and standards, adjusted to account for the unprecedented context in which COVAX has been operating. This will provide a basis against which to assess (a) if the right systems, processes and resources were in place to implement the ToC as intended, in the prevailing context; and (b) the appropriateness of decision making over time. Drawing on a document review, comparator case studies and KIIs, predominantly at global level, this will cover the operational aspects of the ToC as follows:

1. **Management and governance arrangements (EQ2.1.1):** This will ascertain whether the right capabilities, culture and practices were in place to best enable and support the operations of the Office of the COVAX Facility, understand the way accountability works between key stakeholders at different levels, and the reasons/drivers for any failures or successes. As per the evaluability assessment recommendations, it will be important to ensure that the evaluation remains focused on Gavi and the COVAX Facility and COVAX AMC, while also considering the interconnectedness of roles, responsibilities and ways of working between agencies.
2. **Risk management (EQ 2.1.2):** Evaluative enquiry will focus on systematically documenting how risk management processes have been designed and delivered to comprehensively identify and prioritize financial and programmatic risks, and whether these systems and processes enable implementation along the ToC and for the achievement of outcomes and impact. Systems and processes would also be assessed against benchmark comparison frameworks, including Gavi’s business and usual approach to risk management. The assessment will consider the importance of having risk management processes that are appropriate to a highly dynamic context within a public health emergency.
3. **Operational costs (EQ 2.1.3):** This will involve a review of documentation to understand the resource envelope developed by the Secretariat, what was included and what assumptions were made in the budgeting process. It will also review what was approved by the Board to set up and implement the Office of the COVAX Facility. We will conduct analysis of the estimated costs for conducting core processes and benchmark this against established norms/parameters and comparator analysis,

⁵⁰ Daniels, N. and Sabin, J. (2006). *Limits to Health Care: Fair Procedures, Democratic Deliberation, and the Legitimacy Problem for Insurers*. *Philosophy & Public Affairs*, 26 (4). <https://doi.org/10.1111/j.1088-4963.1997.tb00082.x>

⁵¹ Developed by Daniels and Caplan as a policy tool to generate discussion on trade-offs in health policy. Daniels, N., Light, D. W. and Caplan, R. L. (1996). *Benchmarks of Fairness for Health Care Reform*. Oxford University Press; and Caplan, R. L., Light, D. W. and Daniels, N. (1999). *Benchmarks of Fairness: A Moral Framework for Assessing Equity*. *International Journal of Health Services* 29 (4), 853–869. <https://doi.org/10.2190/DBBU-WUC4-Y23L-4LEA>

⁵² e.g. Political Economy Analysis. WaterAid. *Sector Strategy Tool*. https://washmatters.wateraid.org/sites/g/files/jkxoof256/files/PEA%20toolkit_Sector%20Strategy%20Tool.pdf

predominantly based on the cost of administering other global health and emergency response initiatives (e.g. the Gavi Secretariat). We will also collect data through KIIs on whether stakeholders consider that these costs were perceived to be appropriate, the actual level of effort required to manage and implement the Office of the COVAX Facility, and staff availability and working conditions to do so.

4. **Stakeholder engagement (EQ 2.1.4):** Building on the stakeholder mapping under Module 1, additional analysis will map the relationships, influence and interactions between stakeholders during implementation. This will draw on broad-based KIIs and a stakeholder survey to solicit stakeholder perspectives, as well as document review, to assess whether the level of stakeholder engagement and communication is appropriate. We will also benchmark to established standards and comparison to Gavi's business and usual approach to stakeholder engagement and communication, as well as the approaches adopted by other agencies working in global health and emergency response.

A thorough understanding of how well COVAX Facility and COVAX AMC operations have been implemented will enable a number of ToC assumptions to be tested, and process tracing will be set up to explore whether and how these operations have enabled or hampered programmatic implementation and results.

Comparator analysis will also be used to benchmark implementation progress for some programmatic areas of the ToC, as set out in Annex 11.

Process tracing

EQs 2.2–2.5 will use process tracing to assess whether the linkages and assumptions underpinning the ToC have worked as intended, and – where this is not the case – explore how and why not. Specifically, 'inward-out' analysis will be conducted to trace the linkages within the ToC from inputs to activities to outputs. It will take a *monitoring data plus* approach – i.e. it will use existing monitoring data alongside additional verification. Testing will involve gathering evidence on how well the programmatic components have been implemented against the ToC to contribute to change.

This will be complemented by 'outward-in' process tracing to see if observed results are consistent with the ToC and can be traced back to COVAX Facility and COVAX AMC outputs, activities and inputs. In so doing, the method will enable alternative explanations to be ruled out and provide an understanding of how and why the COVAX Facility and COVAX AMC are working to facilitate change. The analysis will enable identification of unintended consequences and barriers and enablers to the achievement of results; in so doing, it will also provide evidence for other EQs (e.g. EQs 3.3 and 3.5).

During the baseline and formative evaluation stage, the focus will be on tracing key activities related to specific programmatic areas – Box 1 provides an example – as well as linkages across programmatic areas, such as coordination between CRD assessments and allocation decisions. An overall analysis will then be conducted to understand, across the ToC, which components are working as intended and which are not. This will draw on the history of decision analysis conducted under Module 1.

Box 1: Example of analysis for resource mobilization programmatic area

With the ToC reflecting the critical thinking behind the resource mobilization strategy, including how the COVAX Facility and COVAX AMC was pitched to external audiences through the investment case, the history of decision and timeline analysis and process tracing will establish when activities were implemented, commitments were secured, funds were received and targets were met.

Drawing on the findings of the PEA from Module 1, we would then seek to systematically test the various assumptions within the ToC to understand the factors related to the mechanism (i.e. the COVAX Facility and COVAX AMC design and its operationalization) and the context that explain how and why the observed results were or were not achieved. Root cause analysis will analyze the underlying causes of observed issues or challenges during implementation. This would be based on substantial document review, KIIs and focus group

discussion, and may draw on other complementary methods to analyze issues and communicate the findings, such as force field analysis.

We would then seek to understand and explore the implications of this analysis, and specifically any delays to fundraising, to the operationalization of other areas of the ToC.

Root cause analysis

Root cause analysis will be used across the scope of work to further explore, analyze and understand the root causes underlying observed challenges or successes identified through a variety of triangulated data sources. This will complement process tracing and other methods by moving beyond identifying what challenges or successes have occurred to determining why a particular challenge or success has occurred. An example is provided in Annex 12.

4.1.3.3 Module 3: Right results

The formative review and baseline study will provide a high-level assessment of results, in order to understand progress towards intermediate outcomes and overall equity goals, and a preliminary assessment of the COVAX Facility and COVAX AMC contribution to these observed results.

Verifying and use of COVAX Reporting Framework indicators

For the formative review and baseline study, although some data is available to report on the emerging results of the COVAX Facility and COVAX AMC, this will be fairly limited and mostly on intermediate outcomes given that COVAX was only established in 2020. Nonetheless, in response to substantial stakeholder interest in exploring this area we will undertake a high-level assessment of results. This will involve triangulation and analysis of the COVAX Reporting Framework with other data (i.e. from documents, information systems, KIIs from global and country stakeholders, country case studies and anecdotal reporting) as part of a process of verification. This will provide a cross-country comparative portfolio analysis of all AMC countries and a preliminary but rounded assessment on the extent to which intended results have been achieved, including whether equity goals have been or are likely to be achieved. This will include analysis of the distribution of and access to vaccines across country income categories, the distribution of and access to vaccines between countries, and the distribution of and access to vaccines within countries (e.g. between geographical areas and population groups).⁵³

Specifically in relation to the assessment of which population groups are receiving vaccines, the evaluation will draw on: the pool of qualitative learning available through WHO regional teams (who host regular webinars to engage with countries through Q&A); country-level learning through the BID Initiative⁵⁴ library (a learning network between countries and between regional and global partners) and via additional learning networks;⁵⁵ and information obtained from Gavi country program and communication staff engagements with country implementers. The proposed country case studies will also supplement this analysis.

This assessment of results will provide a snapshot in time that will be used for comparison in later evaluation processes. It will also highlight areas of high and low performance within the portfolio, the reasons for which will be explored through EQ 4.5 on what can be learned from different country experiences and applied to the COVAX Facility and/or COVAX AMC for the achievement of results.

⁵³ Although the latter is beyond Gavi's control and area of direct responsibility, it is relevant to the achievement of COVAX Facility and COVAX AMC results and overall value for money.

⁵⁴ Bid Initiative. *Resource Library*. <https://bidinitiative.org/resource-library/>

⁵⁵ E.g. Geneva Learning Foundation, TechNet, etc.

Contribution analysis

Contribution analysis is used to understand the likelihood the intervention has contributed to an outcome, observed through a step-by-step process which explores how the contribution would have come about. It uses a broad range of evidence to test this. A more complete description is provided in Annex 12. This will be used to develop findings against EQ 3.4 and frame the overall narrative on COVAX Facility and COVAX AMC results.

Given the relatively early timeline of implementation and the clear appetite among stakeholders to understand the implications of design choices and implementation processes, the formative review and baseline study will involve a high-level assessment of results and partial implementation of contribution analysis.

4.1.3.4 Module 4: Learning

Synthesis and prioritization of lessons learned

In line with the overall methodological approach, the evaluation will: synthesize learning across all evaluation activity; develop synthesis learning products; and facilitate uptake of lessons learned. Learning will be of relevance to COVAX Facility and COVAX AMC course correction, implementation of Gavi 5.0 and future pandemic preparedness, drawing on lessons from other agencies, arrangements and contexts. In so doing, it will respond to EQs 4.1–4.4. The approach to synthesis is outlined in Section 3.4.3, and the validation and prioritization process for lessons learned is detailed in Annex 12.

Particular learning priorities which the formative review and baseline study will seek to generate learning on are as follows.

Operationalising COVAX Facility and COVAX AMC

What did we learn about:

- How governance and organizational structures could be designed to allow the COVAX Facility and COVAX AMC to adapt to changing market dynamics, implementation challenges, etc. across multiple partners in an ever-changing environment, to enable the partners to be successful
- Implementation to date across programmatic and operational elements of the ToC and what the implications of these lessons are for course correction
- The design and implementation of market shaping strategies in a global pandemic context
- The relative balance required between focusing efforts on scaling vaccine procurement and scaling country-level delivery
- The role that COVAX Facility and COVAX AMC has played in procurement within the early introduction and rollout experience⁵⁶
- How the COVAX Facility and COVAX AMC are pivoting and responding to equity concerns – e.g. through adapting allocation, in light of countries' absorption capacities, to avoid vaccine wastage?

Lessons for Gavi 5.0

Did we learn anything about:

- Reaching zero-dose communities through COVAX Facility and COVAX AMC experiences to date
- What it takes to successfully introduce new vaccines in MICs
- Any unintended impacts on routine immunization efforts
- The implications of the design and implementation learning experience generally for Gavi 5.0

⁵⁶ We note that WHO is active in this learning space already.

- If/how barriers to sustainable and equitable new vaccine introductions have changed in light of COVID-19? It will be useful to explore how COVAX is contributing to equitable introduction and use – for example, exploring how the COVAX vaccine delivery strategy is changing in response to respective country absorption capacities in order to avoid waste of vaccines.

Lessons for future pandemic preparedness

The formative review and baseline study will not seek to specifically draw out lessons for future pandemic preparedness or response. These lessons will be drawn out during later midterm evaluations from the various design, operational and programmatic areas of the COVAX Facility and COVAX AMC ToC. Any such analysis will take account of the ways in which future pandemics could differ from COVID-19 and the implications of these differences for extrapolation from the COVID-19 experience.

4.1.4 Data collection

Data collection will necessarily involve a broad review of the available documentation and literature, as well as information sources providing data and evidence of relevance to the evaluation. It will also involve a series of country case studies, where country experiences can be explored in depth.

All evaluation activity will be conducted in as participatory a manner as possible, and the evaluation will engage with a broad set of stakeholder groups/constituencies representing the key bodies and working structures involved in the governance, management and implementation of the COVAX Facility and COVAX AMC. Of particular importance is the need to engage with a broad range of representatives from the Global South, and specifically AMC92 country representatives and civil society representatives, as well as key partners (e.g. AVAT, PAHO, UNICEF and WHO). Such efforts will accommodate the limited time some stakeholders are able to devote to the evaluation, such as by minimizing the number of requests of each stakeholder, holding focus group discussions where feasible, and making use of a web-survey.

For KIIs, it is suggested that stakeholders are purposively sampled – as they were for the evaluability assessment and evaluation design process – in discussion with the ELU, in part based on their availability to engage with the evaluation process and also to ensure that different world views, interests and perspectives are incorporated into the data collected. We present three options for stakeholder engagement through KIIs during the formative review and baseline study, alongside the likely implications to the scope, scale and/or quality of work in Table 11 below. We will seek Gavi's input on these options as we start Phase 1.

Table 11 - Options for stakeholder engagement through KIIs for the formative review and baseline study

Level of stakeholder engagement through KIIs	Implications and potential mitigating actions
1. Anticipated/regular: Broad access to a variety of stakeholders across constituency groups, engaged in and/or knowledgeable about the COVAX Facility and COVAX AMC, as well as COVAX and the ACT-A more generally, at global, regional and country levels. Expected to involve discussions with 50+ stakeholders.	None. Evaluation process can proceed in line with best practice across the full scope of work, as planned.
2. Slightly reduced: More limited access to one or only a few representatives of stakeholder or constituency groups engaged in and/or knowledgeable about the COVAX Facility and COVAX AMC. Stakeholders would still cover the key bodies and working structures identified as critical to engage with. Expected to involve discussions with around 35 stakeholders.	Robustness of evaluation findings may be somewhat compromised if inputs of key stakeholders cannot be fully solicited. Particular issues could be raised with Gavi as they arise to ensure that quality is sufficient. Some narrowing of the scope of work (i.e. to exclude areas where key informants are not available) may help to resolve the issue.
3. Significantly reduced: Only a selection of stakeholders and constituency groups engaged in the COVAX Facility and COVAX AMC would be accessed, including some of those	Robustness of evaluation findings across the entire scope of work highly likely to be substantially compromised, risking the utility of the entire evaluation process. Significant narrowing of

previously identified as critical to engage with. Expected to involve discussions with around 20 stakeholders.

the scope of work to focus only on areas where key informants are may resolve the issue of quality, although the evaluation would likely be unable to report against high-level EQs and develop conclusions on overall performance to generate recommendations of relevance to the Board and PPC.

Country case studies will be used to triangulate the data collected from other sources and extend the data collected to capture country-specific experiences and contexts that will enrich the findings for a number of EQs. They will be particularly helpful in ensuring that the views and perspectives of a broad range of country stakeholders (including health and finance ministries, civil society and humanitarian actors, sub-national, district and local leadership) are captured. It is suggested that countries are purposively sampled to meet this purpose and ensure that a range of diverse country experiences and contexts is incorporated within the evaluation data sample. For instance, we expect this to include AMC92 countries with both high and low allocation or supply of vaccines through COVAX; SFPs with both high and low dependency on COVAX for vaccine procurement; countries with and without local vaccine manufacturing capacity; low- and middle-income countries (LMICs) with/without regional joint procurement initiatives; and AMC92 countries with both high and low vaccination rates. It is also expected that the sample of countries will enable analysis against EQ 4.5 in order to understand the underlying reasons for observed differences between countries emerging from a cross-country portfolio analysis, including how countries across the income spectrum have responded to the realities of sourcing vaccines differently, and which agencies and/or arrangements each has drawn down on, or not, and why.

While travel may not be required for all case studies, given the ongoing pandemic and associated travel restrictions it is also likely that the evaluation team's presence and/or ability to travel to countries will be factored into the selection process.

4.2 Other evaluative activity for Phase 1

4.2.1 Proposed rapid reviews

The overall objectives of the rapid reviews are to: support the Office of the COVAX Facility to flexibly generate learning where it is needed quickly to influence course correction; generate a better understanding of the implementation context; and/or evaluate in detail the efficiency, effectiveness, sustainability or equity of COVAX Facility and COVAX AMC programmatic areas.

The objectives, scope of work and methodology would be determined by the Office of the COVAX Facility/Gavi ELU on a case-by-case basis, depending on implementation needs and opportunities. Summative evaluations may recommend that rapid reviews be undertaken, or they may validate topics suggested by stakeholders. In turn, rapid reviews may inform the ongoing learning function. It is expected that two or three rapid reviews would be conducted within Phase 1 (2022–23), with approximately 40 days of evaluator input (level of effort) over one to two months each. The approach and methodology would be broadly aligned to the formative-summative evaluation, for instance utilizing a theory-based approach and designed to test specific parts of the ToC. It would, however, be implemented in line with the principles and features of real-time evaluation, for instance by collecting data and reporting in real time (or as quickly as practically possible), actively seeking to support different types of learning (e.g. single loop, double loop and triple loop), and by engaging different users in dialogue for sense-making and action planning.⁵⁷

⁵⁷ Rogers, P. (2021, April 15). *Why do we need more real-time evaluation?* Better Evaluation. <https://www.betterevaluation.org/en/blog/why-do-we-need-more-real-time-evaluation>; Ling, T. (2012). *Evaluating complex and unfolding interventions in real time*. *Evaluation*, 18 (1), 79–91; Rogers, P. (2020, December 2020). *Monitoring and Evaluation for Adaptive Management: Real-Time Evaluation*. Better Evaluation. <https://www.betterevaluation.org/en/blog/why-do-we-need-more-real-time-evaluation>

Two potential examples for rapid reviews that could usefully be conducted in 2022 or 2023 to guide course correction are provided in Box 2 below.

Box 2: Potential rapid review topics for 2022 and/or 2023: CRD, humanitarian buffer, securing supply

Increasing priority has been accorded to CRD over time, and efforts are underway to ensure that significant emphasis is placed on this area from 2022 onwards. Similarly, work is currently underway to design, implement and learn from the initial operationalization of the humanitarian buffer.

The formative review and baseline study may confirm the need for such emphasis but, given the limited implementation experience to date, will be ill-timed to provide inputs on how well designed and implemented it has been thus far. However, rapid reviews could be conducted alongside the Office of the COVAX Facility's work to provide ongoing inputs and answer its specific questions on how to design and course correct in these areas, possibly including through the generation of contextual understanding (e.g. on vaccine hesitancy or service delivery barriers as components of CRD). These inputs would be extremely useful and insightful to the following formative-summative evaluation exercise, which would then be well placed to evaluate implementation progress and results. As such, the ability to flex the timing, scope of work and focus of the rapid review to guide learning and course correction would complement and add value over and above the formative-summative evaluation work.

An alternative topic is to focus on Gavi's role and activities in securing supply of COVID-19 vaccines. While much work has been done in this area to date, it is also a high priority area for 2022-23 where, again, a rapid review could likely be structured to support implementation and immediate course correction decision making in real time, as well as supplementing the formative-summative evaluation.

As with other evaluative work, the rapid reviews should be focused on Gavi but recognise the work of other COVAX partners – e.g. for CRD, WHO's role in providing normative guidance, UNICEF and PAHO's role in delivery and supply chain strengthening, and the Global Fund's role in health systems strengthening.

The exact purpose, scope of work and methods for any rapid reviews would need to be finalised at a later date and agreed with Gavi on a case-by-case basis using the criteria mentioned below.

While rapid reviews would be conducted outside of the scope of the formative-summative evaluation work, they could be included within the scope of a single evaluation contract with a service provider or commissioned to external consultants or firms with relevant expertise. There are likely benefits to selecting the former (i.e. with a familiar and 'up to speed' evaluation team, and to ensure coordination across the evaluation activities) but mechanisms should be in place to avoid any real or perceived conflict of interest.⁵⁸

In deciding whether it is appropriate for the formative-summative evaluation providers to conduct a rapid review it is suggested that the following criteria are considered:

- There is a clear use case – i.e. the scope of work will be focused on Gavi and support the generation of learning where it is needed quickly to influence course correction, generate a better understanding of the implementation context, and/or evaluate in detail the efficiency, effectiveness, sustainability or equity of COVAX Facility and COVAX AMC programmatic areas.
- Conducting the rapid review will not duplicate other work and does not pose a conflict of interest for the evaluator(s).
- There is a clear decision point to make use of the information generated by the rapid review.
- There are sufficient resources available (human and financial) to conduct the rapid review to the level of rigor required to appropriately influence the decision being made.
- Conducting the rapid review will support the wider formative-summative evaluation work, and be useful in terms of answering the core EQs.
- The proposed team has technical expertise and availability to conduct the rapid review in the desired time frame.

⁵⁸ A potential conflict of interest may arise where an evaluator supports work to find a solution and then seeks to evaluate it.

Itad will proactively identify any potential conflicts of interest as part of its regular project management risk review, and the involvement of Itad team members will be managed in line with Itad's well-established and rigorous project management and quality assurances procedures. This will include:

- Where identified, Itad will discuss any potential conflicts with the ELU and propose and agree mitigation measures. This may include changes to proposed team members and/or bringing in additional team members who focus exclusively on rapid review(s).
- As Itad's direct reporting line is to the ELU, all terms of reference for rapid reviews and deliverables will be approved and signed off by the ELU. In line with our internal quality assurance procedures, Sam McPherson, a Partner at Itad who is not part of the formative-summative evaluation team, will provide quality at entry (focus on agreeing terms of reference (ToRs) and design), as well as quality at exit to (focus on results and reports) for all deliverables.

4.2.2 Continuous learning

The evaluation should support the continuous learning activity that is ongoing within the Office of the COVAX Facility/Gavi ELU. There is a strong need for the Office of the COVAX Facility/Gavi ELU to learn, both for immediate course correction and for future pandemic preparedness. Ongoing efforts include generating,⁵⁹ collating through the learning library, analyzing and using learning for immediate course correction. The main added value this evaluation can provide is to combine, triangulate through analysis, and synthesize the varied learning outputs emerging from both the Office of the COVAX Facility/ Gavi ELU and this evaluation. Providing this synthesis of learning across the evaluation activity and working to engage user groups will help to facilitate uptake of lessons learned among key stakeholder groups.

Annex 7 identifies three potential evaluation design options, providing different levels of support to the Office of the COVAX Facility/Gavi ELU and an approach for the evaluators and ELU to work together. A light-touch learning support option is recommended, involving support to facilitate 'learning point' meetings, synthesize lessons learned arising from the multi-stage evaluation (MSE) and any additional COVAX Facility evaluation activities, and facilitate validation and prioritization of lessons learned (e.g. through sense-making workshops⁶⁰ and/or recommendation co-creation workshops with relevant teams). This approach would rely on the Office of the COVAX Facility/Gavi ELU to facilitate learning sessions (i.e. to clarify implications of recommendations, what needs to happen, by whom and by when, etc.) and generally support the use of learning for decision making and course correction. This would ensure that the evaluation team helpfully supports the learning function but retains independence from the evaluand in terms of how learning is used.

This collaborative and phased approach can be expected to deliver:⁶¹

1. *single loop learning* by guiding the Office of the COVAX Facility's immediate response to operational problems, such as to reduce fund disbursement delays;
2. *double loop learning* by testing assumptions and change pathways in the ToC to identify root causes and guide adjustment to systems, processes and/or capacities; and
3. *triple loop learning* through facilitated '*learning point*' meetings to understand how learning generated through the MSE is being used to support decision making and course correction.

⁵⁹ Through a combination of formal (e.g. reviews, embedded learning) and informal (e.g. captured via team meetings and calls) opportunities.

⁶⁰ Designed to provide a space for individuals bringing different world view perspectives to question/interrogate lessons arising from data analysis, aiming to minimize bias and promote transformative learning.

⁶¹ Single loop: Identifying discrepancies between planned and actual activities and results and suggesting ways to improve compliance, but without necessarily addressing the cause. Double loop: Exploring root causes of problems to revisit ToC assumptions and adjust systems, processes and/or capacities for implementation. Triple loop: Reviewing what evidence is being used and exploring how learning action happens to support decision making. Tarek, M. (2020, December 12). *06 Single Double Triple Loop Learning*. [Video]. YouTube.

<https://www.youtube.com/watch?v=iWHOSnrsuPo>; Rogers, P. (2021, April 15). *Why do we need more real-time evaluation?* Better Evaluation. <https://www.betterevaluation.org/en/blog/why-do-we-need-more-real-time-evaluation>

We note the potential uncertainty related to how learning priorities and related EQs will be determined and selected (or not) at the different stages of the MSE. See Annex 7 for a proposed decision tree process.

We also note the potential uncertainty regarding which aspects of COVAX-related learning fall under the remit and responsibility of the broader Gavi 5.0 Learning System versus the remit of the COVAX Facility and COVAX AMC MSE. One option could be for the ELU to consider prioritizing learning priorities related to COVAX Facility and COVAX AMC course correction and future pandemic preparedness given its comparative advantage in these content areas, and to consider addressing learning priorities that are relevant specifically to GAVI 5.0 within the remit of the 5.0 Learning System team. These could be commissioned by the Secretariat ELU (rather than included in the COVAX MSE) as centralized and/or decentralized evaluation and/or rapid review pieces, as they align more closely with the broader Gavi 5.0 Learning System portfolio. A communication and learning plan is provided in Annex 16 and a dissemination plan in Annex 17. Annex 7 provides a figure that outlines how the evaluation team propose to collaborate with the ELU during the MSE.

4.3 Recommendations to operationalize the evaluation approach

Assuming that the proposed design options⁶² (see Annex 19) are agreed and accepted, a number of recommendations are made to the Gavi Secretariat and Office of the COVAX Facility to operationalize the evaluation approach – these apply to the formative review and baseline study, but are also relevant to the MSE:

- Gavi should work with other COVAX implementing partners to integrate/align this evaluation process with others to more fully answer bigger-picture questions than this evaluation (which is focused on Gavi and COVAX Facility and COVAX AMC) will be able to – for instance in relation to whether, how and why COVAX as a whole has been able to address power imbalances to ensure equitable access to COVID-19 vaccines.
- Sufficient resources should be devoted to the evaluation function to ensure that:
 - The Office of the COVAX Facility/Gavi ELU is sufficiently capacitated to implement a continuous learning function, as supported by the evaluation, and can help to ensure that methodologies and findings are well understood, as well as guiding and coordinating the formative-summative evaluation work and rapid reviews, particularly if these are conducted by different evaluators.
 - Formative-summative evaluations holistically cover what has worked well and less well in the design, set-up and implementation of the COVAX Facility and COVAX AMC, and in terms of what results have been achieved.
 - Rapid reviews can be conducted, outside of the core formative-summative evaluation work, to respond to particular areas of need.
 - A good governance function is maintained (e.g. with a well-resourced ‘owner’ of the evaluation within the Gavi Secretariat/Office of the COVAX Facility, and continued Evaluation Steering Committee and Evaluation Advisory Committee functions).
 - A strong evaluation team is selected with strong internal capacity to implement the evaluation, with a robust methodology and workplan in place, access to required data, and strong technical advisory support across the scope of work and quality assurance function.
- Efforts should be made by the ELU and others within the Gavi Secretariat and Office of the COVAX Facility to ensure that the required level of stakeholder engagement is achieved in line with the

⁶² These options relate to priority users and uses of the evaluation; EQs; scope of work; design to blend the principles of both (i) a periodic and phased formative-summative evaluation and (ii) real-time evaluation; overarching theory-based, ‘realist-informed’ evaluation approach; envisaged areas of focus within the evaluation scope and how this will evolve over time and at different phases of the evaluation; proposed evaluation methods; and mitigating measures to address risks, challenges and limitations.

evaluation plan developed, for instance to meet expectations for KIIs, workshops, sense-making and co-creation activities.

- The Gavi ELU should maintain contact with COVAX implementing partners and other groups (e.g. the OECD COVID-19 Global Evaluation Coalition) to keep abreast of other evaluation processes and gain access to documents as soon as possible.
- Strengthen data availability on the recipients of COVID-19 vaccines, including disaggregation by vulnerable populations in participant countries, by taking steps to improve eJRF reporting completeness, triangulating data from other sources, and/or undertaking special studies in a sample of countries.

5. Annexes

Annex 1: Glossary of key terms⁶³

- **Accountability** – Obligation of government, public services or funding agencies to demonstrate to citizens that contracted work has been conducted in compliance with agreed rules and standards or to report fairly and accurately on performance results vis-à-vis mandated roles and/or plans. This may require a careful, even legally defensible, demonstration that the work is consistent with the contract terms. Projects commonly focus on upward accountability to the funding agency, while downward accountability involves making accounts and plans transparent to the primary stakeholders. Ensuring accountability is one part of the function of monitoring and evaluation (learning and management are the other two).
- **Activity** – Actions taken or work performed in a project to produce specific outputs by using inputs, such as funds, technical assistance and other types of resources.
- **Adaptive management** – A process that integrates project design, management and monitoring to provide a framework for testing assumptions, adaptation and learning.
- **Assumption** – A condition that needs to be met for the successful achievement of objectives. Assumptions are hypotheses about why we believe change will happen in a certain way, and why we believe certain conditions are necessary and sufficient for a change to happen.
- **Attribution** – The causal link of one thing to another; e.g. the extent to which observed (or expected to be observed) changes can be linked to a specific intervention in view of the effects of other interventions or confounding factors.
- **Baseline information** – Information – usually consisting of facts and figures collected at the initial stages of a project – that provides a basis for measuring progress in achieving project objectives and outputs.
- **Baseline study** – An analysis describing the situation in a project area – including data on individual primary stakeholders – prior to a development intervention. Progress (results and accomplishments) can be assessed and comparisons made against it. It also serves as an important reference for the completion evaluation.
- **Benchmark** – Reference point or standard against which performance or achievements can be compared. A benchmark might refer to what has been achieved in the past, by other comparable organizations, or what could reasonably have been achieved under the circumstances.
- **Capacity** – The ability of individuals and organizations to perform functions effectively, efficiently and in a sustainable manner.
- **Capacity building** – The processes through which capacity is created.
- **Causal relationship** – A logical connection or cause-and-effect linkage existing in the achievement of related, interdependent results. Generally, the term refers to plausible linkages, not statistically accurate relationships.
- **Causality analysis** – The study of cause-and-effect relations that link an intervention to its impacts.
- **Effect** – Intended or unintended change resulting directly or indirectly from a development intervention.

⁶³ Drawn primarily from: a range of sources, including International Fund for Agricultural Development (IFAD). (2020). *Managing for Impact in Rural Development: A guide for project M&E*. <https://www.ifad.org/documents/38714182/39723123/toc.pdf/e7c718e2-56b9-4f60-b404-3f31448a38a2>

- **Effectiveness** – A measure of the extent to which a project attains its objectives at the goal or purpose level; i.e. the extent to which a development intervention has attained, or is expected to attain, its relevant objectives efficiently and in a sustainable way.
- **Efficacy** – The extent to which the project’s objectives were achieved or expected to be achieved, taking into account their relative importance.
- **Efficiency** – A measure of how economically inputs (funds, expertise, time, etc.) are converted into outputs.
- **Evaluability** – The extent to which an activity or project can be evaluated in a reliable and credible fashion.
- **Evaluation** – A systematic (and as objective as possible) examination of a planned, ongoing or completed project. It aims to answer specific management questions and to judge the overall value of an endeavour and supply lessons learned to improve future actions, planning and decision making. Evaluations commonly seek to determine the efficiency, effectiveness, impact, sustainability and relevance of the project or organization’s objectives. An evaluation should provide information that is credible and useful, offering concrete lessons learned to help partners and funding agencies make decisions.
- **External evaluation** – Conducted by evaluator(s) outside of the implementing project/programme team, lending it a degree of independence, objectivity and often technical expertise.
- **End-term evaluation** – An external evaluation that occurs after project completion.
- **Facilitator** – A person who helps members of a group conduct a meeting in an efficient and effective way but who does not dictate what will happen.
- **Feedback** – The transmission of evaluation findings to parties for whom it is relevant and useful so as to facilitate learning. This may involve the collection and dissemination of findings, conclusions, recommendations and lessons learned from experience. Specifically in the context of evaluation, to return and share the evaluation results with those who participated in the evaluation.
- **Formative evaluation** – Evaluation conducted during implementation to improve performance. It is intended for managers and direct supporters of a project.
- **Goal** – The higher-order programme or sector objective to which a development intervention, such as a project, is intended to contribute. Thus it is a statement of intent.
- **Impact** – The changes in the lives of rural people, as perceived by them and their partners at the time of evaluation, plus sustainability-enhancing change in their environment to which the project has contributed. Changes can be positive or negative, intended or unintended.
- **Implementing partners** – COVAX core implementing partners represent CEPI, Gavi, UNICEF and WHO.
- **Indicator** – Quantitative or qualitative factor or variable that provides a simple and reliable basis for assessing achievement, change or performance. A unit of information measured over time that can help show changes in a specific condition. A given goal or objective can have multiple indicators.
- **Indirect effects** – The unplanned changes brought about as a result of the intervention.
- **Joint evaluation** – An evaluation to which different institutions and/or partners contribute.
- **Learning** – Reflecting on experience to identify how a situation or future actions could be improved and then using this knowledge to make actual improvements. This can be individual or group-based. Learning involves applying lessons learned to future actions, which provides the basis for another cycle of learning.

- **Lessons learned** – Knowledge generated by reflecting on experience that has the potential to improve future actions. A lesson learned summarizes knowledge at a point in time, while learning is an ongoing process.
- **Market shaping** – Used in a consistent way with the Gavi Market Shaping Strategy 2021-2025 (i.e. efforts that aim to make life-saving vaccines and other immunisation products more accessible and affordable for lower-income countries). However, we note that the scope of activities intended for and implemented through the COVAX Facility and COVAX AMC may not be as comprehensive as for the Gavi Market Shaping Strategy 2021-2025.
- **Means of verification** – The expected source(s) of information that can help answer the performance question or indicators. This is found in the third column of the standard logframe. It is detailed further in the monitoring and evaluation (M&E) matrix.
- **Method** – The specific tools for analysis used to conduct the evaluation.
- **Midterm evaluation** – Evaluation performed towards the middle of the period of implementation of the intervention.
- **Monitoring** – The regular collection and analysis of information to assist timely decision making, ensure accountability and provide the basis for evaluation and learning. It is a continuing function that uses methodical collection of data to provide management and the main stakeholders of an ongoing project or programme with early indications of progress and achievement of objectives.
- **Monitoring and evaluation** – The combination of monitoring and evaluation which together provide the knowledge required for: (a) effective project management and (b) reporting and accountability responsibilities.
- **Objective** – A specific statement detailing the desired accomplishments or outcomes of a project at different levels (short to long term). A good objective meets the criteria of being impact-oriented, measurable, time-limited, specific and practical.
- **Objective hierarchy** – The different levels of objectives, from activities up to goal. If the project is designed well, realization of each level of objectives in the hierarchy should lead to fulfilment of the project goal.
- **Objectively verifiable indicators** – A group of criteria (not necessarily measurable) used to verify the degree of accomplishment (foreseen or actual) of the sectoral purpose, the objective, and the inputs and outputs of a project. They can be quantitative, and therefore both verifiable and measurable, or qualitative, and therefore only verifiable.
- **Outputs** – The tangible (easily measurable, practical), immediate and intended results to be produced through sound management of the agreed inputs. Examples of outputs include goods, services or infrastructure produced by a project and meant to help realize its purpose. These may include changes, resulting from the intervention, that are needed to achieve outcomes.
- **Participation** – One or more processes in which an individual (or group) takes part in specific decision making and action, and over which s/he may exercise specific controls. It is often used to refer specifically to processes in which primary stakeholders take an active part in planning and decision making, implementation, learning and evaluation. This often has the intention of sharing control over the resources generated and responsibility for their future use.
- **Participatory evaluation** – A broad term for the involvement of primary and other stakeholders in evaluation. The primary focus may be the information needs of stakeholders rather than the donor.
- **Partner** – The organization in the project country with which the funding agency collaborates to achieve mutually agreed objectives. Partners may include host country governments, local and

international non-governmental organizations (NGOs), universities, professional and business associations, private businesses, etc.

- **Performance** – The degree to which a development intervention or a development partner operates according to specific criteria/standards/guidelines or achieves results in accordance with stated goals or plans.
- **Precondition** – Condition that must be fulfilled before a project can become effective (e.g. when disbursement against the loan becomes possible).
- **Process evaluation** – An evaluation aimed at describing and understanding the internal dynamics and relationships of a project, programme or institution.
- **Process monitoring** – The activities of consciously selecting processes, selectively and systematically observing them to compare them with others, and communicating about what has been observed to learn how to steer and shape the processes.
- **Project** – An intervention that consists of a set of planned, interrelated activities designed to achieve defined objectives within a given budget and a specified period of time.
- **Project management** – The process of leading, planning, organising, staffing and controlling activities, people and other resources in order to achieve particular objectives.
- **Purpose** – The positive improved situation that a project or programme is accountable for achieving.
- **Qualitative** – Something that is not summarized in numerical form, such as minutes from community meetings and general notes from observations. Qualitative data normally describe people's knowledge, attitudes or behaviours.
- **Quantitative** – Something measured or measurable by, or concerned with, quantity; expressed in numbers or quantities.
- **Reach** – The beneficiaries and other stakeholders of a development intervention, whether sectors, groups of people or geographic areas of the country or region.
- **Relevance** – The extent to which the objectives of a project are consistent with the target group's priorities and the recipients' and donors' policies.
- **Reliability** – Consistency or dependability of data and evaluation judgements, with reference to the quality of the instruments, procedures and analyses used to collect and interpret evaluation data. Information is reliable when repeated observations using the same instrument under identical conditions produce similar results.
- **Resources** – Items that a project has or needs in order to operate, such as staff time, managerial time, local knowledge, money, equipment, trained personnel and sociopolitical opportunities.
- **Result** – The measurable output, outcome or impact (intended or unintended, positive or negative) of a development intervention.
- **Review** – An assessment of the performance of a project or programme, periodically or on an as-needed basis. A review is more extensive than monitoring but less extensive than evaluation.
- **Sample** – The selection of a representative part of a population in order to determine parameters or characteristics of the whole population.
- **Situation analysis** – The process of understanding the status, condition, trends and key issues affecting people, ecosystems and institutions in a given geographic context at any level (local, national, regional, international).

- **Stakeholder** – An agency, organisation, group or individual who has a direct or indirect interest in the project/programme, or who affects or is affected positively or negatively by the implementation and outcome of it.
- **Stakeholder participation** – Active involvement by stakeholders in the design, management and monitoring of the project. Full participation means all representatives of key stakeholder groups at the project site become involved in mutually agreed, appropriate ways.
- **Sustainability** – The likelihood that the positive effects of a project (such as assets, skills, facilities or improved services) will persist for an extended period after the external assistance ends.
- **Target** – A specified objective that indicates the number, timing and location of that which is to be realised.
- **Target group** – The specific group for whose benefit the project or programme is undertaken, closely related to impact and relevance.
- **Theory of Change** – A ‘Theory of Change’ explains how activities are understood to produce a series of results that contribute to achieving the final intended impacts. It can be developed for any level of intervention – an event, a project, a programme, a policy, a strategy or an organization.
- **Triangulation** – Use of a variety of sources, methods or field team members to cross-check and validate data and information to limit biases.
- **Validity** – The extent to which something is reliable and actually measures up to or makes a correct claim. This includes data collection strategies and instruments.
- **Validation** – The process of cross-checking to ensure that the data obtained from one monitoring method are confirmed by the data obtained from a different method.

Annex 2: Document review and bibliography

Table 12 - Types and quantities of documents reviewed by the Itad team

Document type	Number*
Gavi documents	116
COVAX partnership documents	72
Core partner documents	27
Independent documents	24
Academic literature	36
Grey literature	84
TOTAL NUMBER	359

*as of 26 November 2021

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Executive board

- "Advance Market Commitment Resource Mobilisation", Gavi, 15 December 2020
- "Annex A - Alternative options explored for the administration of the Facility and key reasons for not exploring further", Gavi, 30 July 2020
- "Annex A - COVAX AMC pledges and donations", Gavi, 1 October 2021
- "Annex A - COVAX AMC support to India - Data Tables", Gavi 15 December 2020
- "Annex A - Implications and Anticipated Impact", Gavi, 15 December 2020
- "Annex A - Report of the Chief Executive Officer", Gavi, 16 June 2021
- "Annex A: AMC eligible economies", Gavi, 15 December 2020
- "Annex A: Implications/Anticipated impact", Gavi, 29 September 2020
- "Annex A: Terms of the COVAX AMC", Gavi, 30 July 2020
- "Annex B - Allocation Humanitarian Buffer and Contingency provision", Gavi, 30 September
- "Annex B - COVAX Budget 2021 and three-year forecast", Gavi, 15 December 2020
- "Annex B–Risk analysis", Gavi, 30 July 2020
- "Annex B: COVAX Reporting Framework", Gavi, 1 May 2021
- "Annex B: Pledges to the Gavi COVAX AMC", 15 December 2020
- "Annex B: The COVAX AMC Group: proposed eligible economies", Gavi, 30 July 2020
- "Annex C - COVAX Reporting Framework", Gavi, 15 December 2020
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- "Annex C: COVAX Risk Report", Gavi, 23 June 2021
- "Annex D: COVAX Country Participation Model: Risk Considerations", Gavi, 23 June 2021
- "Annex D: Facility resourcing needs over time", Gavi, 30 July 2020
- "Annex E - Draft Learning Agenda", Gavi, 15 December 2020
- "Annex E- Draft Gavi 5.0 Theory of Change and Learning Priorities", Gavi, 15 December 2021
- "Annex E: Participation model options", Gavi, 23 June 2020
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- "COVAX AMC SUPPORT TO INDIA", Gavi, 15 December 2020
- "COVAX BUFFER FOR HIGH-RISK GROUPS IN HUMANITARIAN SITUATIONS", Gavi, 22 March 2021
- "COVAX Facility operationalisation and vaccine program", Gavi, 15 December 2020
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"COVAX Resource Mobilisation Update", Gavi, 28 September 2021
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"COVID-19: GAVI'S IMMEDIATE AND INTERIM RESPONSE", Gavi, 11 May 2020
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"Gavi 5.0: An Overview of Key Issues", Gavi, 28 September 2021
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"Gavi Alliance Audit and Finance Committee – COVAX 11 December 2020 Virtual Meeting", Gavi, 11 December 2020
"Gavi Alliance Audit and Finance Committee – COVAX 2 March 2021 Virtual Meeting", Gavi, 2 March 2021
"Gavi Alliance Audit and Finance Committee – COVAX 25 March 2021 Virtual Meeting", Gavi, 25 March 2021
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Governance Committee

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- "Shareholders Council Meeting 2", Gavi, 28 January 2021
- "Shareholders Council Meeting 3", Gavi, 18 March 2021
- "Shareholders Council Meeting 4", Gavi, 18 May 2021
- "Shareholders Council Meeting 5", Gavi, 14 July 2021

Advance Market Commitment Engagement Group

- "Advance Market Commitment Engagement Group Meeting 4", Gavi, 17 May 2021
- "Advance Market Commitment Engagement Group Meeting 1", Gavi, 19 November 2020
- "Advance Market Commitment Engagement Group Meeting 2", Gavi, 27 January 2021
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- "Advance Market Commitment Engagement Group Meeting 5", Gavi, 12 July 2021

Programme and Policy Committee

- "Gavi Alliance Programme and Policy Committee Meeting", Gavi, 28 October 2020
- "Gavi Alliance Programme and Policy Committee Meeting", Gavi, 26 May 2020
- "COVAX Buffer for high-risk groups in humanitarian situations", Gavi, 1 March 2021
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- "The Vaccine Alliance – Risk and Assurance Report 2020", Gavi, 2021
- "Annex B – CSCE Theory of Change and Strategic Initiative", Gavi, 2021 [DIAGRAM]
- "The Gavi COVAX AMC an Investment Opportunity", Gavi
- "COVAX Facility Governance – Slide Deck", Gavi, 17 March 2021
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“COVAX Facility AMC Engagement Group Summary Minutes of Meeting 1”, COVAX, 1 November 2020

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Annex 3: People interviewed

The following 26 key informants (Table 13) took part in interviews as part of the evaluability assessment/evaluability design phase:

Table 13 - List of key informant interview participants

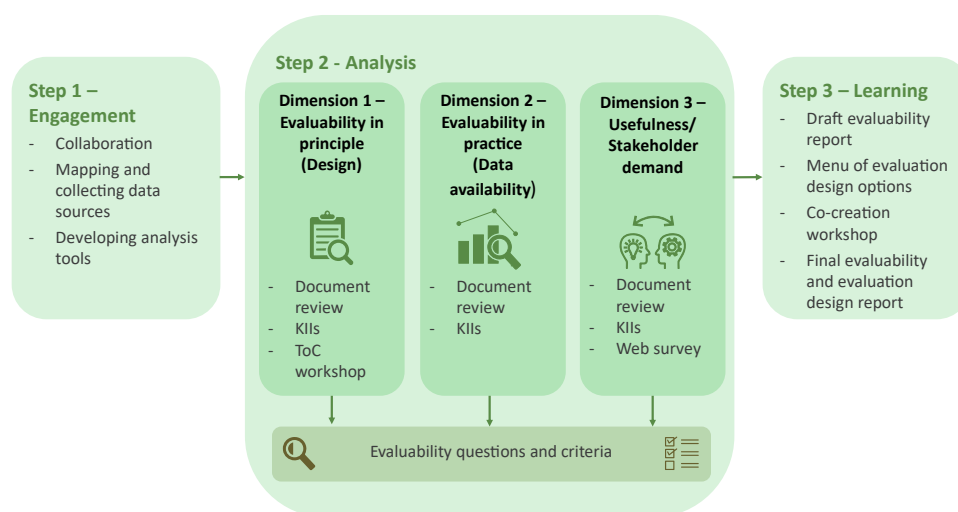
Individual	Organization	Stakeholder group
Prashant Yadav	Center for Global Development	Academic/research
Arthur Baker	Arthur Baker	Academic/research
Lia Tadesse (and Ministerial Team)	Ministry of Health, Ethiopia	AMC92 representative
Nel Druce	United Kingdom Foreign, Commonwealth and Development Office	AMC92 representative
Arvind Mungur	United Kingdom Foreign, Commonwealth and Development Office	AMC92 representative
Kate O'Brien	WHO	COVAX technical partner
Andrew Jones	UNICEF	COVAX technical partner
Soumya Swaminathan	WHO	COVAX technical partner
Richard Hatchett	CEPI	COVAX technical partner
Ann Lindstrand	WHO	COVAX technical partner
Benjamin Shreiber	UNICEF	COVAX technical partner
Claudia Nannei	WHO	COVAX technical partner
Orin Levine	Bill & Melinda Gates Foundation	Donor, foundation or bank
Violaine Mitchell	Bill & Melinda Gates Foundation	Donor, foundation or bank
Seth Berkley	Gavi	Gavi Secretariat
Aurelia Nguyen	Gavi	Gavi Secretariat
Derrick Sim	Gavi	Gavi Secretariat
Santiago Cornejo	Gavi	Gavi Secretariat
Thabani Maphosa	Gavi	Gavi Secretariat
Marie-Ange Saraka-Yao	Gavi	Gavi Secretariat
Andrew Freeman	Gavi	Gavi Secretariat
Sanne Wendes	Gavi	Gavi Secretariat
Brenda Killen	Gavi	Gavi Secretariat
Laura Crow	Gavi	Gavi Secretariat
Sai Prasad	Developing Countries Vaccine Manufacturers Network	Private sector
Gabriel Mesa (and Ministerial Team)	Colombian Ministry of Health	SFP representative

Annex 4: Evaluability assessment (EA) methodology and process

Our EA approach rests on the methodology developed by Dr Rick Davies⁶⁴ – a member of our Technical Advisory Group - involving three steps (Figure 3):


1. **Engagement** – Through the inception phase, in collaboration with the Gavi ELU, we identified boundaries and agreed on the outputs of the EA and identified the resources available for the assessment and options for stakeholder engagement (Step 1).
2. **Analysis** – Systematic analysis of evidence across three dimensions (in principle, practice and usefulness) against a set of evaluability questions and criteria (Step 2).⁶⁵
3. **Learning** – Synthesis, analysis and feedback of initial findings to stakeholders, culminating in recommendations to strengthen the evaluability of the COVAX Facility and COVAX AMC (Step 3).

Figure 3 - EA approach



The following sections detail each step in the EA, setting out the purpose, approach and outputs for each. Table 14 sets out the list of EQs from the RfP which have been grouped by module to provide an organizing framework to structure the evaluation design.⁶⁶ The EA is conducted on these EQs.



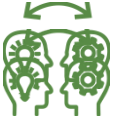
Table 14 - EQs used for EA

Module	EQ	EQs (Bold = headline EQ)
 1. Right things: Design	1	Is the intervention design and logic underpinning the COVAX Facility and AMC clear, relevant, evidence-based and understood by all stakeholders?
	1.1	To what extent and how did external stakeholders and COVAX partners contribute to the original program design, and what impact did this have?
		How effective and appropriate is the design of the COVAX Facility and AMC, including proposed market shaping strategies, to achieving the intervention outcomes and goals?
	1.2	A - To what extent does the intervention logic capture the geopolitical context shaping supply, demand and access to COVID-19 vaccines (including related to intellectual property rights and patents, trade secrets and transparency, and sharing of data and technology)? B - How strategic and appropriate were the choices and trade-offs made in designing the intervention?
	1.3	What assumptions underpin the intervention logic, and have they been upheld?
	2	To what extent have the COVAX Facility and AMC been implemented as intended and efficiently, including in a timely and agile manner?
	2.1	What risks/challenges were encountered during the implementation of the COVAX Facility and AMC, and how were these mitigated/resolved?

⁶⁴ Davies, R. (2021). *Evaluability Assessment As Jigsaw Puzzle*. PowerPoint presentation for the ADA, Government of Austria.

⁶⁵ Given the breadth of stakeholders involved in the design and operationalization of the COVAX Facility and COVAX AMC, and the evolving nature of the COVAX Facility’s organizational arrangements, we examine the third dimension of usefulness through the prism of two corresponding ‘sub-dimensions’: stakeholder demands and expectations; and the wider organization and external context.

⁶⁶ As explained in the inception report, the evaluation questions have been slightly adapted and refined from those in the RfP. The purpose of this has not been to steer the evaluation scope of work but to structure the questions.

 <p>2. Right way: Implementation</p>	2.2	How appropriate and relevant are the COVAX Facility and AMC management structures and governance arrangements?
	2.3	Are the actual and opportunity costs of implementing the COVAX Facility and AMC reasonable and appropriate?
	2.4	To what extent have relevant external stakeholders been engaged throughout implementation in the manner intended, and what factors affected engagement?
	2.5	How effective was the resource mobilization strategy of the COVAX Facility and AMC?
	3	To what extent have the COVAX Facility and AMC contributed to the achievement of intended outcomes and impact?
 <p>3. Right results: Outcomes and impact</p>	3.1	To what extent have the intended intermediate outcomes been achieved? A - Did COVAX Facility market shaping strategies achieve their intended objectives (including rapid development of vaccine portfolio, increased manufacture, pooled demand, secure supply)? B - How well were the COVAX Facility & AMC able to solicit participation of SFP and AMC countries? C - Did the COVAX Facility & AMC allocate vaccines among participating economies and countries as intended? D - Were COVAX Facility & AMC efforts to support vaccination program delivery in-country provided as intended?
	3.2	To what extent have the COVAX Facility and AMC achieved (or to what extent are they likely to achieve) intended high-level outcomes and impact? A - Rapidly increased equitable distribution of vaccines across countries, including in fragile and conflict-affected states. B - Delivering vaccination to intended vulnerable populations in participant countries. C - Reducing morbidity, mortality and the socioeconomic impact of the pandemic. D - Ending the acute phase of the COVID-19 pandemic globally.
	3.3	How have the COVAX Facility and AMC contributed to the achievement of these outcomes and impact within the global geopolitical and economic landscape of actors involved in development and delivery of COVID-19 vaccines?
	3.4	What evidence is there to suggest unintended consequences and results beyond the ToC, including in relation to any effects of the COVAX Facility and AMC on routine immunization efforts?
	4	What lessons can be drawn on the design and implementation of the COVAX Facility and AMC?
	4.1	To what extent have systems and processes been established to capture, collate and disseminate learning around identified needs/gaps?
	4.2	What are the most important barriers and enablers to achieving the outcomes and goals in the COVAX ToC at all levels of implementation?
 <p>4. Learning</p>	4.3	What are the priority learnings from implementation of the COVAX Facility and AMC to inform: A - course correction for the COVAX Facility and AMC? B - implementation of Gavi 5.0? C - future pandemic preparedness and vaccine innovation and access?
	4.4	What can be learned from other agencies/arrangements/contexts and applied to the COVAX Facility and/or AMC for the achievement of intended outcomes and impact?

Step 1 – Engagement

This step was completed in the inception phase and communicated in our inception report, submitted to Gavi on 17 September 2021.

Collaboration

Throughout the evaluative process we have had regular (and much appreciated) communications with the focal points from the ELU. Based on ELU feedback indicating that the staff of COVAX implementing partners were extremely overstretched and had asked the evaluators to be respectful of their time and priorities, we did not hold wider stakeholder interviews during the inception phase.

This posed a number of challenges/limitations related to stakeholder buy-in to both the evaluation process and its findings and access to data, which we have sought to address through broad-based engagement in the current phase of work to assess evaluability and design the MSE – see Section 1.

Mapping and collecting data sources

Our main data sources are documents, information systems and stakeholders.

Documents: Over 300 documents pertaining to COVAX, and specifically the COVAX Facility and COVAX AMC, have been reviewed and logged. Relevant documents, covering a broad scope, were sourced through the ELU and via desk research of select journals, media and gray literature. The materials identified included reports, meeting slide decks and Board documents, as well as media articles and academic material. These documents have been used to build our understanding of the institutional context of the assignment and evaluation, laying the foundation for the EA. A bibliography is provided in Annex 2.

Information systems: A number of information systems have informed the assignment. This includes the COVAX Reporting Framework and COVAX Facility and COVAX AMC MEL Strategy, WHO's Coronavirus (COVID-19) Dashboard, the Access to COVID-19 tools funding commitment tracker, UNICEF's COVID-19 Vaccine Market Dashboard, and Our World in Data statistics and research on COVID-19 vaccinations. We have also reviewed vaccine development and supply landscapes/forecasts to understand what information has been, and can be expected to continue to be, made available over time (available from CEPI, UNICEF and other sources), as well as information on other vaccine development and/or purchase agreements outside of COVAX (as tracked through the UNICEF COVID-19 Vaccine Market Dashboard and various other trackers).⁶⁷

Stakeholders: Through a stakeholder mapping and hierarchical card sorting (HCS) exercise conducted with the ELU we: (a) identified stakeholders of direct relevance to the COVAX Facility and COVAX AMC – this includes those engaged in implementation, management, governance, and oversight, as well as external stakeholders; (b) elicited the significant differences between the identified stakeholders; and (c) considered the implications of these differences for conducting the EA. This highlighted a highly complex stakeholder landscape, with multiple interactions between different stakeholders across the various technical areas of the COVAX Facility and COVAX AMC and its management, governance and oversight functions.

A sample of 26 stakeholders representing the key bodies and structures engaged in the governance, oversight and management of the COVAX Facility and COVAX AMC, as well as external stakeholders with a good understanding of the global health and COVAX-specific landscape, was interviewed during the evaluability assessment/evaluability design phase. Further, a web-survey (designed to facilitate much broader-based inputs to the evaluability assessment/evaluability design process) was distributed to over 300 stakeholders. A summary of the web-survey outputs and analysis is provided in Annex 5.

Across the stakeholder interviews and web-survey we have sought to ensure strong representation from a mix of core implementing partners of COVAX, other stakeholders engaged in COVAX operationalization, and a broader set of stakeholders with an interest in COVAX. This includes:

- Country governments, including: high and higher-middle-income SFPs via the COVAX Shareholders Council; low and lower-middle-income countries via the AMC Engagement Group; and OECD donors via the AMC Investors Group and OECD COVID-19 Global Evaluation Coalition
- Community and civil society, including via the Platform for ACT-A Civil Society & Community Representatives, Gavi CSO Constituency, and members of the civil society Global Financing Facility (GFF) resource and engagement hub
- Multilateral organizations, including the COVAX core implementing partners (CEPI, Gavi, UNICEF and WHO), development banks and other representatives engaged in the governance, oversight and management of the COVAX Facility and COVAX AMC
- Private sector, including collaborations/networks of vaccine manufacturers and individuals and representatives of organizations engaged in the engaged in the governance, oversight and management of the COVAX Facility and COVAX AMC

⁶⁷ For instance, the Regulatory Affairs Professionals Society COVID-19 Vaccine Tracker and the New York Times Coronavirus Vaccine Tracker.



- Others, including public health institutes/agencies, foundations and a number of academic, research and training institutes.

Analysis framework

Table 15 presents our EA framework.⁶⁸ This includes a set of evaluability questions and criteria which we have applied in order to understand how and how robustly each of the EQs can be responded to, or rather how problematic it will be to answer each of the EQs, and how useful it will be to do so. This has provided the basis on which to refine and prioritize the EQs, highlight the weaknesses and gaps that are critical to address for a robust evaluation to proceed, and develop an appropriate evaluation design.

⁶⁸ This draws on the experience and expertise of Dr Rick Davies, for instance as set out in Davies, R. (2021). *Evaluability Assessment As Jigsaw Puzzle*. PowerPoint presentation for the ADA, Government of Austria.

Table 15 - EA framework

Evaluability dimension	Evaluability question	Evaluability criteria
 Evaluability in principle	1 Are the planned activities, short- to medium-term outcomes, objectives and goals of the COVAX Facility and COVAX AMC clearly defined and time-bound?	Clarity
	2 To what extent does the ToC present measurable short- to medium-term outcomes, objectives and goals, and proposed steps towards achieving these?	Clarity
	3 Is there a causal chain which clearly connects the COVAX Facility and COVAX AMC to the final impact goal, and is it likely that the intervention goal(s) will be achieved within the intervention time frame?	Plausibility
	4 Are there valid and reliable indicators at each stage of the ToC which will capture what is expected to happen?	Validity/Reliability
	5 Are the assumptions underlying the ToC clear, particularly with regard to external actors?	Contextualization
	6 Are there linkages in the ToC that are most critical to the success of the project and should therefore be the focus of a future evaluation?	Testability
	7 Are changes to the intervention captured by the ToC, and does it provide an accurate reflection of the current intervention logic?	Consistency
	8 Is the ToC articulated in a consistent way across project documentation and between stakeholders?	Consistency/ Agreement
	9 Are there expected to be multiple interactions between different project components and/or stakeholders, thereby complicating attribution of causes and identification of effects? How clearly defined are the expected interactions?	Complexity
 Evaluability in practice	10 Is the business/investment case for the COVAX Facility and COVAX AMC clearly articulated?	Data availability
	11 Is complete data on the a) activities, b) outputs, c) outcomes and d) goals expressed in the ToC?	Data availability
	12 Are monitoring and measurement frameworks functional, reliable and able to collect data against all indicators and with sufficient frequency? Does a relevant baseline or counterfactual exist and can it feasibly be applied? What data and methods are required?	Baseline and counterfactual relevance and availability
	13 Are the populations and groups receiving vaccines through the intervention identifiable, and is this data available at an appropriate frequency?	Data availability (relative to product end users)
	14 Is adequate disaggregated data (e.g. for gender and other equity-related indicators) available to measure impact against the ToC outcomes?	Data availability (relative to end user groups)

Evaluability dimension	Evaluability question	Evaluability criteria	
	16	What is the current capacity of staff, systems and processes to collect/generate data relevant to the ToC, results framework and desired outcomes and goals, using approaches that enable consistent analysis against these?	Capacity
Usefulness – stakeholder demand	17	Have the key stakeholders and primary evaluation audiences been identified, and will they participate in the evaluation design and evaluation process?	Participation
	18	What EQs are of interest to which stakeholders, and is it realistic for the evaluation to answer them?	Expectations
	19	What are stakeholder expectations for the evaluation design and process? How will this affect their participation?	Expectations
	20	What is the current capacity of COVAX staff, systems and processes to synthesize and interpret data and generate learning from it?	Capacity
	21	How much time is available to conduct data collection, and what are the scheduling opportunities and constraints?	Resources
	22	To what extent are stakeholders able to use new learning to adapt interventions within existing project cycles?	Capacity
Usefulness – wider institutional context	23	Are there opportunities for the evaluation to have an influence, and how does the time frame of the intervention affect the ability to extract useful learnings and lessons?	Capacity
	24	Are sufficient resources available to support an evaluation?	Resources
	25	What coordination is required with other bodies involved in the implementation of the COVAX Facility and COVAX AMC?	Participation
	26	Are external events able to be identified and taken into account?	External events



Step 2 – Analysis

Dimension 1 – Evaluability in principle (design)

To assess evaluability in principle, we analyzed the evidence base underlying the COVAX Facility and COVAX AMC ToC, including an examination of assumptions, enablers and challenges, the perceived objectives of the intervention among stakeholders, and the timeframe of the ToC. This involved a substantial document review, as well as KIIs with stakeholders to gain insights into their understanding of the ToC and how it aligns with implementation of the COVAX Facility and COVAX AMC. Through this process we gained a good understanding of the evolving nature of the design of the COVAX Facility and COVAX AMC, reflected in iterations of the ToC, and different stakeholder perceptions of how the intervention logic is intended to work. We then sought to develop a single model that is evaluable but represents the diversity of stakeholder perceptions elicited during the EA. This process was not completed, but sufficient progress was made to present a ToC that can guide further discussion during the formative review and baseline study.

Dimension 2 – Evaluability in practice (data availability)

We appraised the availability of data (from documents, KIIs and information systems) to understand whether it is sufficient to test the COVAX Facility and COVAX AMC ToC and answer each of the EQs. This has resulted in the identification of some gaps that need to be filled in order to evaluate progress against the desired pathways of the COVAX Facility and COVAX AMC ToC, which are the basis of recommendations detailed below to strengthen data quality and availability.

Dimension 3 – Usefulness (stakeholder demand/wider institutional context)

This component of the EA has provided an understanding of: the demands, requirements and expectations of stakeholders (internal and external to the COVAX Facility and COVAX AMC) for the MSE; how the COVAX Facility and COVAX AMC intervention is structured; the context in which it operates; and how monitoring data is currently used and absorbed through learning pathways.

Step 3 – Learning: Synthesis, implications of EA and MSE design

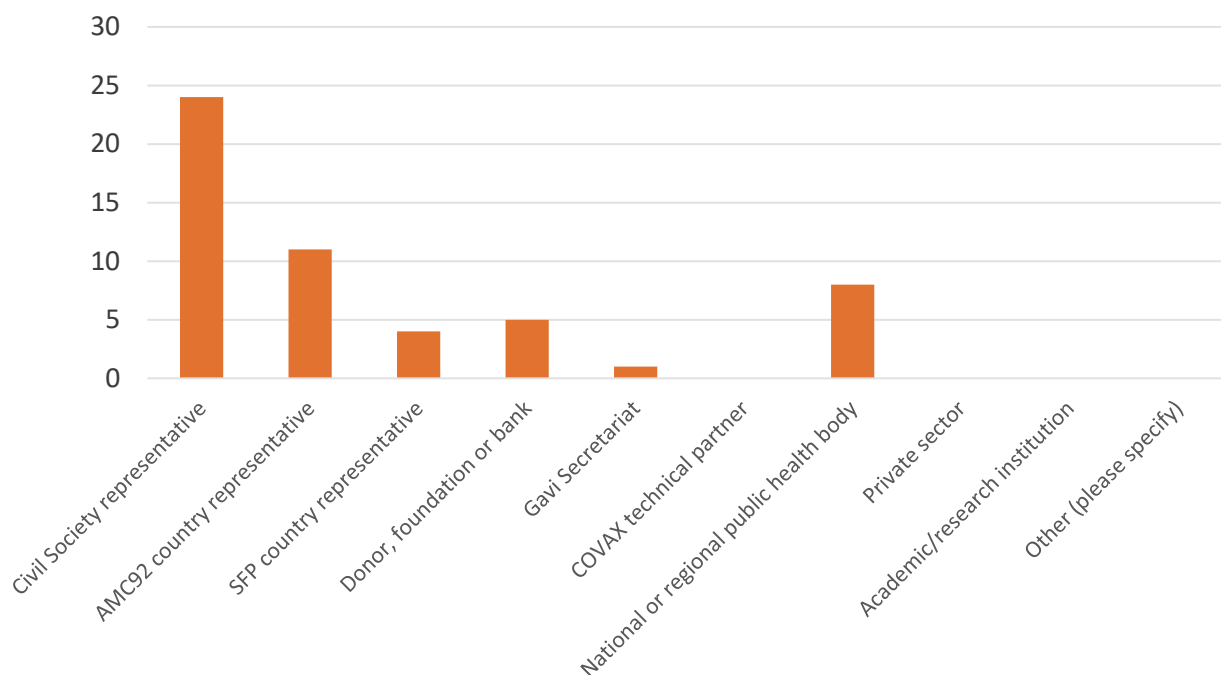
We present this synthesis of evaluability findings in Section 2.5 – ‘Overall evaluability’ – and implications of the EA for MSE design in Section 3.3 – ‘Strategic direction and methodological design approach of the multi-stage evaluation’. To arrive at this synthesis, module leads shared results of their module EAs during evaluation team workshops, as well as a proposed approach to MSE design. During workshops we explored the implications of findings and discussed design options together. The content of these discussions on the relative pros and cons of different design approaches is summarized above.

Annex 5: Web-survey outputs and analysis

A web-survey was designed to facilitate much broader-based inputs to the evaluability assessment/evaluability design process. In total, 54 participants responded to the web-survey.

Figure 4 (below) gives a summary of the web-survey’s respondents, grouped by stakeholder type. Civil society represents the largest respondent group (24 out of the 54 total respondents). No responses were received from those representing COVAX technical partners, the private sector, academic/research institutions, or those categorized as ‘other’.

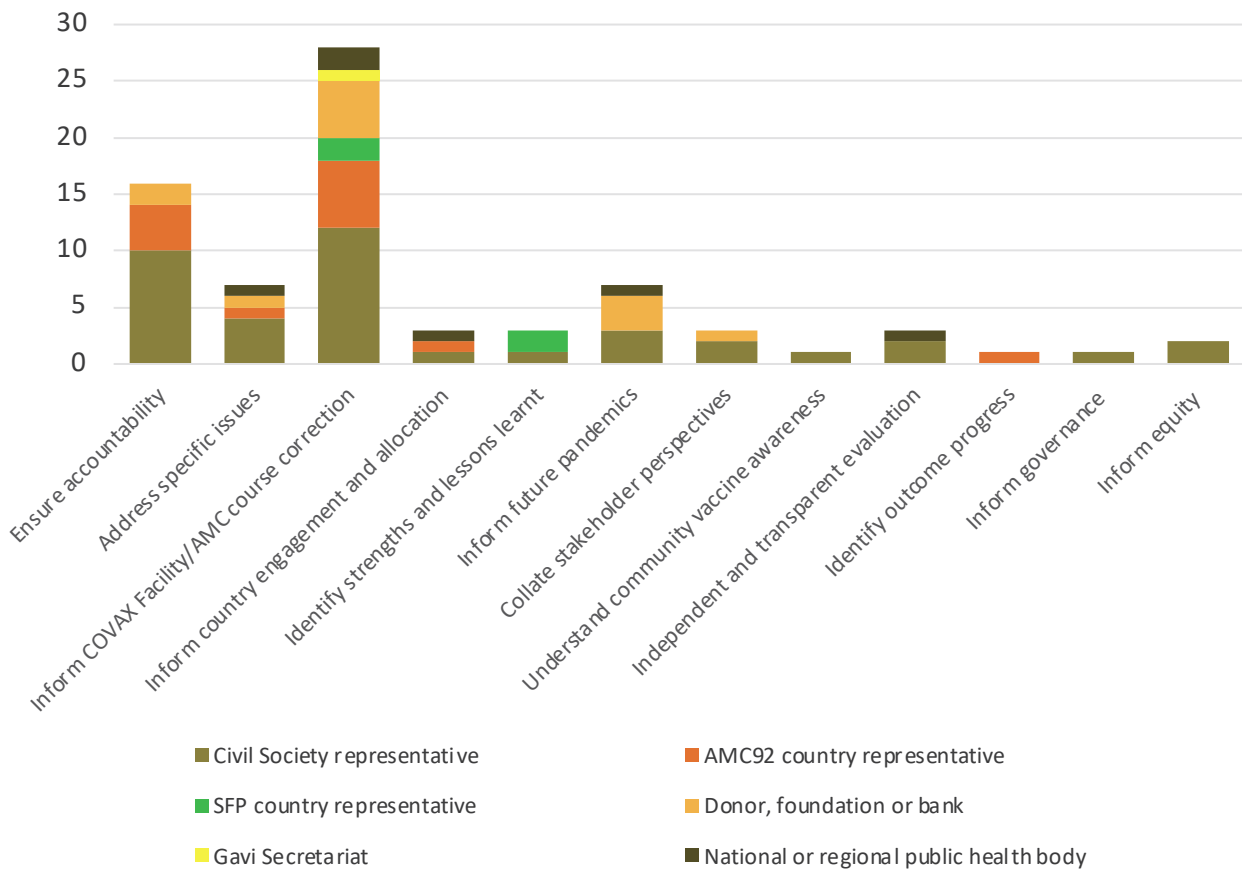
Figure 4 - Summary by respondent type



The figures below represent the respondents’ answers to each of the four survey questions.⁶⁹ Across all results no clear trend or viewpoint could be attributed to a particular stakeholder group.

⁶⁹ Where individuals did not respond to a specific question, or where entire groups did not respond to the survey, data points were excluded from the following analysis.

Figure 5 - Overall, how do you think an evaluation of the COVAX Facility and COVAX AMC can add the most value?



Participants were asked to identify where they thought the evaluation would add the most value. A broad range of suggestions were presented by respondents and are shown in Figure 5. Respondents most frequently referenced course correction for the COVAX Facility and COVAX AMC as an area of value (n=28). This was followed by using the evaluation to ensure accountability (n=16). The broad range of responses to this question indicate the perceived value and usefulness of undertaking this evaluation. Importantly the value of this evaluation is broad, and its usefulness is perceived by a range of different stakeholder groups.

Figure 6 - Does this scope of work respond well to your needs?

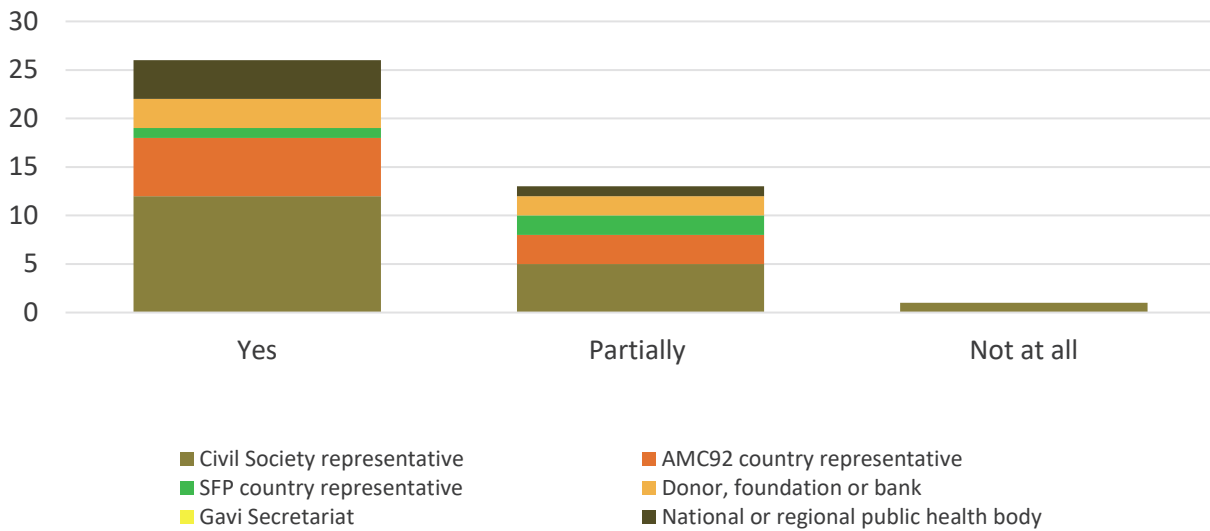


Figure 6 illustrates how well the current scope of the evaluation meets different stakeholder needs. From these survey results we can see that the scope broadly meets participants’ needs, with only one participant stating that their needs were not met. However, 13 participants did express that, currently, their needs are only partially met. Figure 7 (below) looks to elaborate on these potential gaps in need.

Figure 7 - Is anything missing from the evaluation scope?

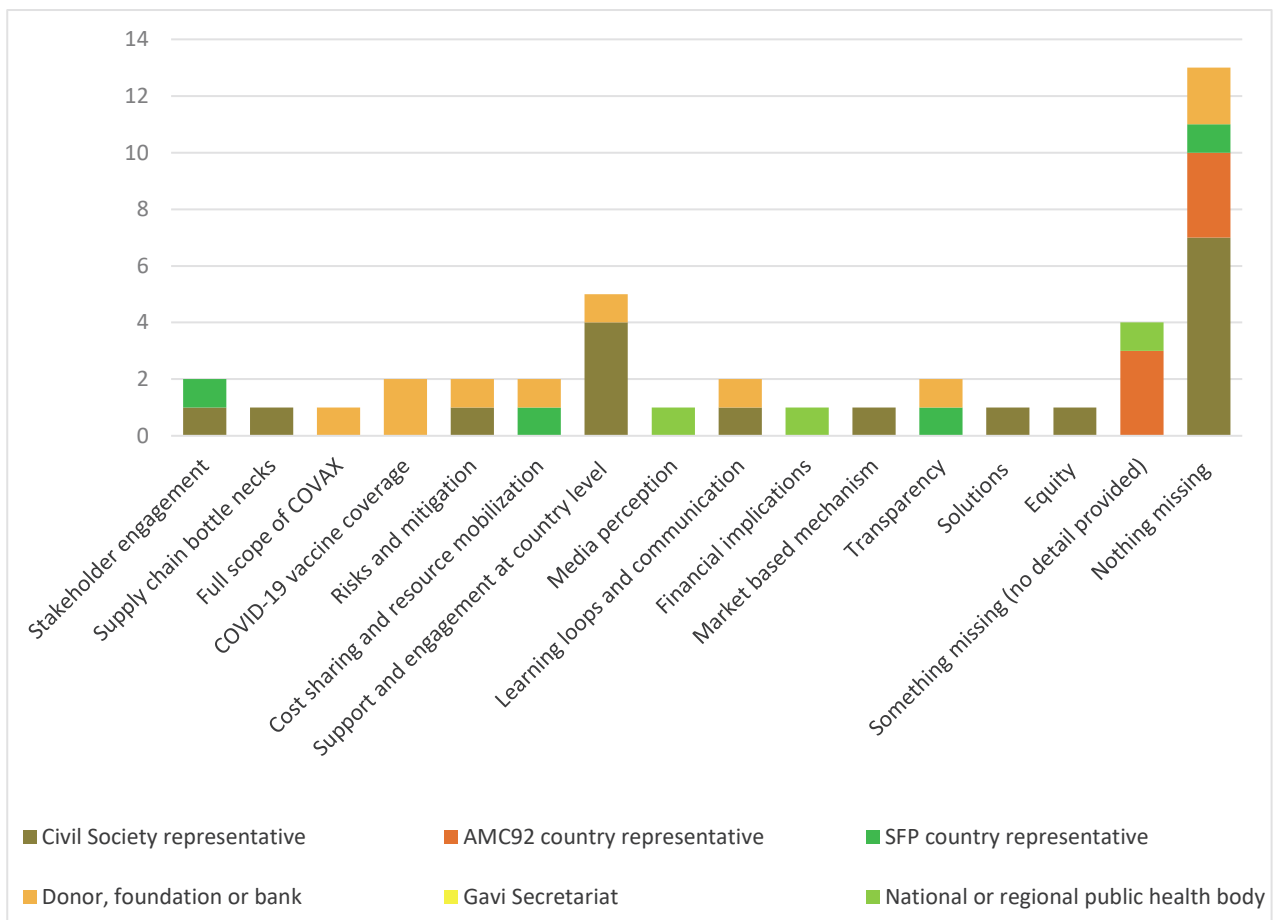
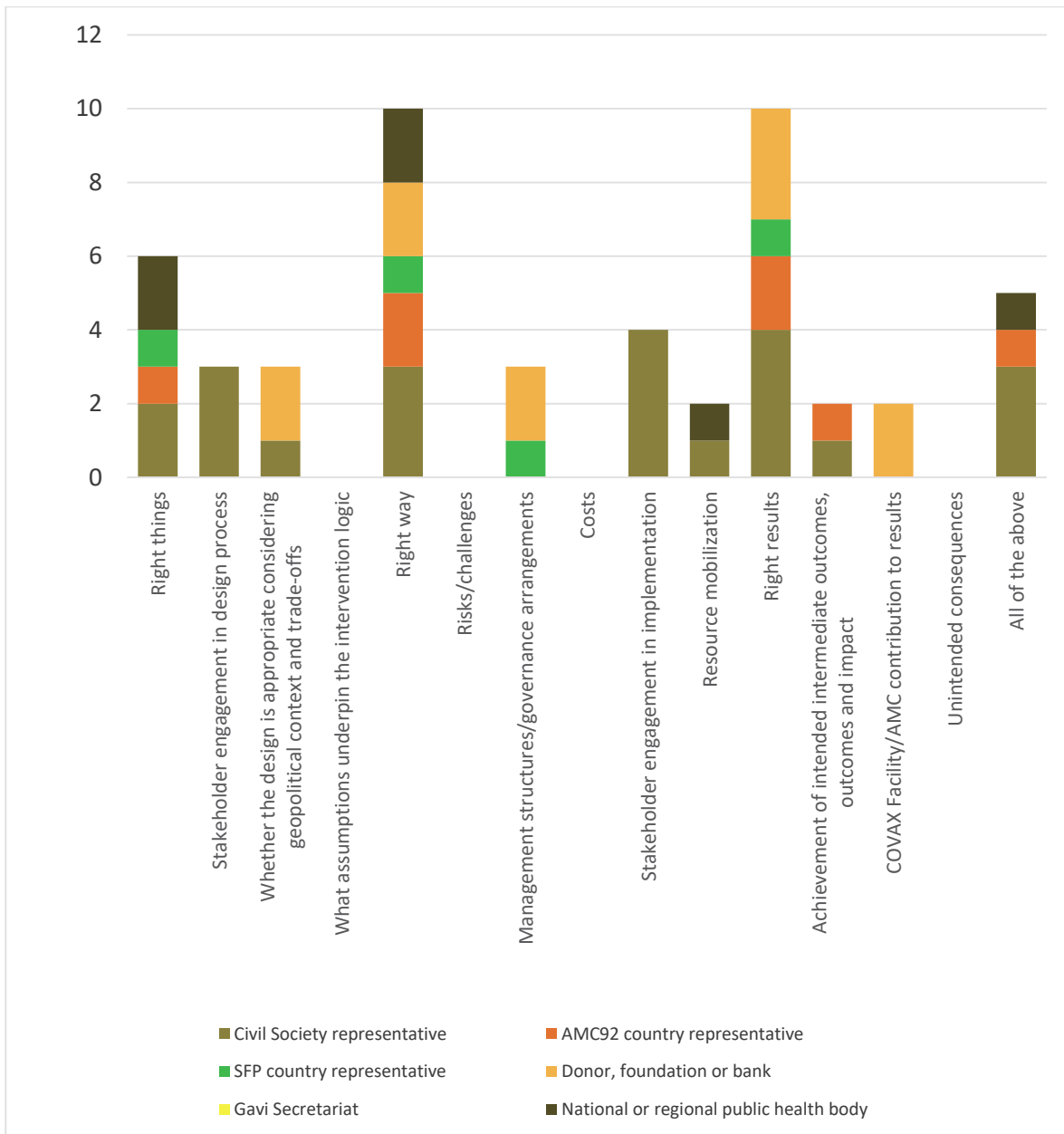


Figure 7 shows that the perceived gaps in the current evaluation scope varied heavily between participants. As a result, 14 separate gaps were identified. The most frequently proposed gap was an exploration of the COVAX Facility and COVAX AMCs ‘support and engagement at a country level’ (n=5). Thirteen participants responded that nothing was missing from the evaluation scope, while four responded that they felt something was missing but did not provide any further details.

Finally, respondents were asked what areas of the scope of work they consider most important (Figure 8). Here the overarching modules areas (right things, right way, right results) were most frequently selected by respondents. While the results indicate that all three areas were considered important, right ways and right results were seen as the most valuable (n=10 for both areas). Five participants stated that all areas of the evaluation scope were important.



Figure 8 - What areas of the scope of work do you consider most important?





Annex 6: Findings from the EA

Table 16 presents a summary, linked to the sections above, of how problematic it is expected to be to answer each EQ, where green indicates no major anticipated problems, yellow indicates some anticipated problems, and red indicates that there are major anticipated problems.

Table 16 - EA scoring by EQ

Module	EQ	EQs (Bold = headline EQ)	Evaluability in principle*	Evaluability in practice	Usefulness
 1. Right things: Design	1	Is the intervention design and logic underpinning the COVAX Facility and AMC clear, relevant, evidence-based and understood by all stakeholders?	Intervention logic and causal chain presented in the draft ToC is draft and evolving, but overall sufficiently clear, plausible and coherent to be evaluated	Significant documentation & data available to assess design	Significant interest in EQ and very useful to answer
	1.1	To what extent and how did external stakeholders and COVAX partners contribute to the original program design, and what impact did this have?		Data available and possible to verify stakeholder engagement	Significant external interest in EQ and important to understand equity in process
	1.2	How effective and appropriate is the design of the COVAX Facility and AMC, including proposed market shaping strategies, to achieving the intervention outcomes and goals? A - To what extent does the intervention logic capture the geopolitical context shaping supply, demand and access to COVID-19 vaccines (including related to intellectual property rights and patents, trade secrets and transparency, and sharing of data and technology)? B - How strategic and appropriate were the choices and trade-offs made in designing the intervention?		Significant documentation & data available to assess design, potentially drawing on narrow counterfactual and comparator analysis	Significant interest in EQ and very useful to answer
	1.3	What assumptions underpin the intervention logic, and have they been upheld?		Assumptions have not been comprehensively documented	Critical to answer EQ
 2. Right way: Implementation	2	To what extent have the COVAX Facility and AMC been implemented as intended and efficiently, including in a timely and agile manner?	Significant documentation & data available to answer EQ, although data not always aligned and need to interpret implementation progress in context**	Significant stakeholder interest in EQ and critical to answer	
	2.1	What risks/challenges were encountered during the implementation of the COVAX Facility and AMC, and how were these mitigated/resolved?	Significant documentation & data available on risk management systems, what risks were encountered and how mitigated	Internal and external stakeholder interest in EQ and very useful to answer	
	2.2	How appropriate and relevant are the COVAX Facility and AMC management structures and governance arrangements?	Documentation & data available, but some processes and decision points not recorded in/aligned to official documentation	Internal stakeholder interest in EQ and very useful to answer	
	2.3	Are the actual and opportunity costs of implementing the COVAX Facility and AMC reasonable and appropriate?	Actual cost data available and potential to benchmark to comparators to assess appropriateness. Analysis of opportunity costs needs boundaries and may be problematic	Not raised as a particular priority by stakeholders, although relevant to consider	
	2.4	To what extent have relevant external stakeholders been engaged throughout implementation in the manner intended, and what factors affected engagement?	Data available and possible to verify stakeholder engagement	Significant external interest in EQ and important to understand equity in process	
	2.5	How effective was the resource mobilization strategy of the COVAX Facility and AMC?	Some documentation & data available but gaps in data on why any delays occurred which may be challenging to fully answer	Significant stakeholder interest in EQ and critical to answer	

 <p>3. Right results: Outcomes and impact</p>	<p>3</p> <p>To what extent have the COVAX Facility and AMC contributed to the achievement of intended outcomes and impact?</p>	<p>Despite some challenges, overall there is sufficient data available to assess results</p>	<p>Significant stakeholder interest in EQ and critical to answer</p>
	<p>3.1</p> <p>To what extent have the intended intermediate outcomes been achieved? A - Did COVAX Facility market shaping strategies achieve their intended objectives (including rapid development of vaccine portfolio, increased manufacture, pooled demand, secure supply)? B - How well was the COVAX Facility & AMC able to solicit participation of SFP and AMC countries? C - Did the COVAX Facility & AMC allocate vaccines among participating economies and countries as intended? D - Were COVAX Facility & AMC efforts to support vaccination program delivery in-country provided as intended?</p>	<p>Significant data available to verify intermediate outcomes, including from COVAX Reporting Framework and external sources</p>	<p>Although there is significant external stakeholder interest in this area, much is already known and has been reported on. There is appetite, however, for an independent perspective which understands the full spectrum of implementation and decision points connected to results</p>
	<p>3.2</p> <p>To what extent have the COVAX Facility and AMC achieved (or to what extent is it likely to achieve) intended high-level outcomes and impact? A - Rapidly increased equitable distribution of vaccines across countries, including in fragile and conflict-affected states. B - Delivering vaccination to intended vulnerable populations in participant countries. C - Reducing morbidity, mortality and the socioeconomic impact of the pandemic. D - Ending the acute phase of the COVID-19 pandemic globally.</p>	<p>Some gaps in data are anticipated on disaggregated vaccine coverage by population group, and measures to assess health and socioeconomic impacts are yet to be finalized. The vision to 'end the acute phase of the pandemic' has also not been specifically defined</p>	<p>Significant stakeholder interest in EQ to understand the performance of the COVAX Facility and COVAX AMC in achieving results. Critical to answer</p>
	<p>3.3</p> <p>How have the COVAX Facility and AMC contributed to the achievement of these outcomes and impact within the global geopolitical and economic landscape of actors involved in development and delivery of COVID-19 vaccines?</p>	<p>Will require significant data collection and efforts to disentangle the complexity of the evaluand and broader context to make causal claims and establish contribution</p>	<p>Significant stakeholder interest in the contextualization of results and the implications for results of the COVAX Facility and COVAX AMC situation within a broader ecosystem of global players. Critical to answer</p>
	<p>3.4</p> <p>What evidence is there to suggest unintended consequences and results beyond the ToC, including in relation to any effects of the COVAX Facility and AMC on routine immunization efforts?</p>	<p>Significant data available on unintended consequences and possible to assess further to fully answer EQ</p>	<p>Significant stakeholder interest in consequences on routine immunization efforts. Critical to answer</p>
 <p>4. Learning</p>	<p>4</p> <p>What lessons can be drawn on the design and implementation of the COVAX Facility and AMC?</p>	<p>Overall, there is sufficient data available to answer the learning EQs</p>	<p>Significant stakeholder interest in EQ and critical to answer</p>
	<p>4.1</p> <p>To what extent have systems and processes been established to capture, collate and disseminate learning around identified needs/gaps?</p>	<p>Learning systems and processes are clear and data is available to assess how well they are working</p>	<p>EQ not considered a high priority for evaluation to focus on</p>
	<p>4.2</p> <p>What are the most important barriers and enablers to achieving the outcomes and goals in the COVAX ToC at all levels of implementation?</p>	<p>Some barriers and enablers are documented internally and externally, but further data collection is required to fully answer EQ</p>	<p>Significant stakeholder interest in EQ and critical to answer</p>
	<p>4.3</p> <p>What are the priority learnings from implementation of the COVAX Facility and AMC to inform: A - course correction for the COVAX Facility and AMC? B - implementation of Gavi 5.0?</p>	<p>Significant learning already generated but not systematically documented and shared. Particular gap in learning on how equitable distribution is being achieved at country level</p>	<p>Significant stakeholder interest in EQ and critical to answer</p>

	C - future pandemic preparedness and vaccine innovation and access?		
4.4	What can be learned from other agencies/arrangements/contexts and applied to the COVAX Facility and/or AMC for the achievement of intended outcomes and impact?	Good potential to use comparator analysis for learning, particularly to address gap in learning on how equitable distribution is being achieved at country level	Significant stakeholder interest in EQ and critical to answer

* Not relevant for all EQs. Where this is the case the table cell has been merged with evaluability in practice.

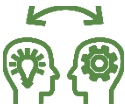

** These challenges apply to all EQs in Module 2 but, for the sake of brevity, are not repeated.

Table 17 presents a summary, linked to the sections above, of how problematic it is expected to be to answer each evaluability assessment question (EAQ), where green indicates no major anticipated problems, yellow indicates some anticipated problems, and red indicates that there are major anticipated problems.

Table 17 - Evaluability assessment scoring by EAQ

Evaluability dimension	Evaluability questions	Right things	Right way	Right results	Learning
 Evaluability in principle	1: Are the planned activities, short- to medium-term outcomes, objectives and goals of the COVAX Facility and COVAX AMC clearly defined and time-bound?	Goals consistent, activities and strategies evolving		Overarching impacts consistent, but intended outcomes and activity targets have evolved	N/A
	2: To what extent does the ToC present measurable short- to medium-term outcomes, objectives and goals, and proposed steps towards achieving these?			Reporting framework aligned with draft ToC	N/A
	3: Is there a causal chain which clearly connects the COVAX Facility and COVAX AMC to the final impact goal, and is it likely that the intervention goal(s) will be achieved within the intervention time frame?			Causal chain clear at high level but needs to be unpacked for each programmatic component. Achievement of final impact goal unlikely within current time frame	N/A
	4: Are there valid and reliable indicators at each stage of the ToC which will capture what is expected to happen?			Reporting framework aligned with draft ToC but some impact metrics are not fully developed	N/A
	5: Are the assumptions underlying the ToC clear, particularly with regard to external actors?			Limited assumptions presented in the ToC	N/A
	6: Are there linkages in the ToC that are most critical to the success of the project and should therefore be the focus of a future evaluation?			All linkages are critical, but with some priority outputs & intermediate outcomes to achieving overall equity goal	N/A
	7: Are changes to the intervention captured by the ToC, and does it provide an accurate reflection of the current intervention logic?			Draft ToC is updated, still evolving. Nested ToCs for programmatic areas need to be developed	N/A
	8: Is the ToC articulated in a consistent way across project documentation and between stakeholders?			Two draft versions consistent and shared	N/A
	9: Are there expected to be multiple interactions between different project components and/or stakeholders, thereby complicating attribution of causes and identification of effects? How clearly defined are the expected interactions?			Many project components and multiple interactions of different stakeholders make the attribution of causes to identified effects challenging	

Evaluability dimension	Evaluability questions	Right things	Right way	Right results	Learning
 <p>Evaluability in practice</p>	10: Is the business/investment case for the COVAX Facility and COVAX AMC clearly articulated?	Investment case exists for the Facility and AMC			N/A
	11: Is complete data on the (a) activities, (b) outputs, (c) outcomes and (d) goals expressed in the ToC?	Reporting framework mentions data sources for most indicators – not for all ToC assumptions	Multiple data sources on activities and outputs through governance documents and other routine reporting; Reporting Framework data available against most outcomes and goals		N/A
	12: Are monitoring and measurement frameworks functional, reliable and able to collect data against all indicators and with sufficient frequency?	Reporting Framework indicators are developed for all ToC goals, but some impact metrics are not yet fully developed			N/A
	13: Does a relevant baseline or counterfactual exist and can it feasibly be applied? What data and methods are required?	No useful overall counterfactual but alternative design choice counterfactuals and comparators are feasible.			N/A
	14: Are the populations and groups receiving vaccines through the intervention identifiable, and is this data available at an appropriate frequency?	N/A	Data is available for many countries which received vaccines, but population groups are unknown and frequency of complete reporting is variable		N/A
	15: Is adequate disaggregated data (e.g. for gender and other equity-related indicators) available to measure impact against the ToC outcomes?	N/A			N/A
16: What is the current capacity of staff, systems and processes to collect/generate data relevant to the ToC, results framework and desired outcomes and goals, using approaches that enable consistent analysis against these?	N/A	Significant demands on COVAX Facility staff and in-country vaccine delivery staff, but overall capacity is unspecified		N/A	

Evaluability dimension	Evaluability questions	Right things	Right way	Right results	Learning
 <p>Usefulness – stakeholder demand</p>  <p>Usefulness – wider institutional context</p>	17: Have the key stakeholders and primary evaluation audiences been identified, and will they participate in the evaluation design and evaluation process?	Stakeholder groups defined, availability for participation limited, although enthusiasm and agreement to do so			
	18: What EQs are of interest to which stakeholders, and is it realistic for the evaluation to answer them?	Design timeline; 'what if' for key design decisions; & stakeholder engagement in design – reasonably realistic for MSE to answer them	Different areas of the scope (operational and programmatic) identified by stakeholders. Realistic for them to be answered within the structure of the evaluation design	Results questions are of interest to stakeholders, but through the lens of design and implementation choices link to results; realistic for MSE to answer them	Stakeholders have identified interest in different areas of scope – these insights have been integrated into the communications and learning plan
	19: What are stakeholder expectations for the evaluation design and process? How will this affect their participation?	N/A	No particular expectations expressed	No particular expectations expressed	None expressed. KIIs appeared to welcome opportunity to share views during EA

Evaluability dimension	Evaluability questions	Right things	Right way	Right results	Learning
	20: What is the current capacity of COVAX staff, systems and processes to synthesize and interpret data and generate learning from it?	N/A			Clear appetite to generate learning. Capacity to generate and use learning appears high. Capacity to synthesize across learning pieces in a holistic way is a current gap
	21: How much time is available to conduct data collection, and what are the scheduling opportunities and constraints?				Stakeholders have limited time to engage in evaluation process, but potential for evaluation design to accommodate sufficient time for data collection
	22: To what extent are stakeholders able to use new learning to adapt interventions within existing project cycles?	N/A			COVAX Facility and COVAX AMC are used to a continuous learning approach and are doing this organically. Limitations on stakeholder engagement time could limit learnings being used
	23: Are there opportunities for the evaluation to have an influence, and how does the time frame of the intervention affect the ability to extract useful learnings and lessons?	N/A	N/A	N/A	Yes, though changeable opportunities. Will require close collaboration with ELU to keep reassessing learning priorities and communication opportunities
	24: Are sufficient resources available to support an evaluation?	N/A	N/A	N/A	Based on EA experience, yes. ELU is responsive and available
	25: What coordination is required with other bodies involved in the implementation of the COVAX Facility and COVAX AMC?				Significant coordination is required across the COVAX implementing partners (WHO, UNICEF, PAHO, CEPI), as well as stakeholders engaged in the governance and management of the COVAX Facility and COVAX AMC
	26: Are external events able to be identified and taken into account?				Learning from other relevant external evaluations (e.g. evaluative work to be commissioned by UNICEF, the World Bank and some OECD members as coordinated by the COVID-19 Global Evaluation Coalition) or other COVID-19 emergency responses such as personal protective equipment (PPE) procurement and provision, etc.

Annex 7: Determining the overall evaluation design

Dealing with complexity

In recent years there has been an increasing appreciation in public policy and evaluation that policy approaches have been inadequate, unable to deal with uncertainty, and ‘failing to appreciate the complexity of human behavior and the systems in which we live’. The problems we face are understood to be unintended consequences of intervening in complex systems, including ‘ecosystems, financial markets, and energy markets, or societal phenomena such as urbanization and migration’.⁷⁰

The now commonplace view that the social world is composed of complex systems has resulted in policy and programming responses that more overtly acknowledge uncertainty, as evidenced by increasing use of adaptive policy and adaptive management approaches. This has created new challenges for evaluation, and the more complex the intervention, the more difficult will be the evaluation.

The COVAX Facility and COVAX AMC is a system that encompasses many interacting global agents, serving a range of different functions across a number of sectors, requiring feedback from recipient countries and communities to refine ideas and adjust approaches. Based on the findings from the EA and drawing on a range of literature in this area, the system can be usefully framed as one that moves from being ‘complicated’ at the activity and output end of the results chain to one that is increasingly ‘complex’ as it progresses towards impact.⁷¹

In results chain terms, the relationships at the activity and output end of the chain are comparatively straightforward. There is established knowledge and understanding of how Gavi and other implementing partners of COVAX translate financial inputs into activities and outputs related to the shaping of markets for the equitable distribution and use of vaccines. While this requires factors outside of Gavi’s direct sphere of control, which infers complexity, this part of the COVAX Facility and COVAX AMC system may be conceived as merely complicated.⁷² Even when we consider that the system design is regularly subject to evolution this can still be characterized as complicated rather than complex.

Towards the outcome and impact parts of the results chain, the COVAX Facility and COVAX AMC is in the ‘real world’ – i.e. where the achievement of results is subject to the context in which the intervention is operating, at global, regional and country levels. Making progress here entails change that is iterative, adaptive and non-linear. This is a messy space that can be characterized as highly complex.⁷³

⁷⁰ Sanderson, I. (2002). *Evaluation, Policy Learning and Evidence-Based Policy-Making*. Public Administration, 80, 1–22; ECD. (2017). *Debate the Issues: Complexity and policy making*. OECD Insights, OECD Publishing, Paris. <http://www.oecd.org/economy/debate-the-issues-complexity-and-policy-making-9789264271531-en.htm>

⁷¹ For instance, using the Stacey matrix and David Snowden’s Cynefin framework.

For the Stacey matrix see Zimmerman, B.(2001). *Ralph Stacey’s Agreement & Certainty Matrix*. Better Evaluation.

https://www.betterevaluation.org/en/resources/guide/ralph_staceys_agreement_and_certainty_matrix

For the Cynefin framework see Snowden, D. J. and Boone, M. E. (2007, November). *A Leader’s Framework for Decision Making*. Harvard Business Review. <https://hbr.org/2007/11/a-leaders-framework-for-decision-making>

⁷² Complicated systems assume an ordered universe and involve a number of interrelated parts, which interact in broadly predictable ways.

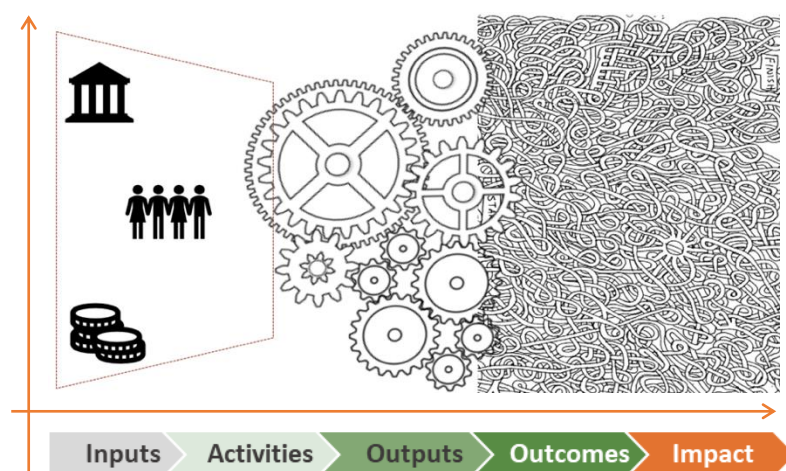
Interventions in these systems expect the parts and process to ‘function in a predictable way if the whole intervention [continued below] is to succeed. The processes are broadly predictable and outputs arrive at outcomes in well-understood ways’. Ling, T. (2012). *Evaluating complex and unfolding interventions in real time*. Evaluation, 18 (1), 79–91. <https://doi.org/10.1177/1356389011429629>

Complicated interventions (evaluands) have these characteristics: implemented through multiple agencies, multiple simultaneous causal strands, and different causal mechanisms operating in different contexts Rogers, P. J. (2008). *Using Programme Theory to Evaluate Complicated and Complex Aspects of Interventions*. Evaluation, 4 (1), 29–48. <https://doi.org/10.1177/1356389007084674>

⁷³ Complex systems are unordered, and function in ways that are much less predictable. The relationship between cause and effect may not be immediately apparent and can only be determined through emerging patterns. There will usually be multiple perspectives from different actors in complex systems, and learning about change in these systems requires aspects of social learning. These systems are non-linear, may respond in non-proportional ways, and may be in constant flux or indeed resist change, affected by context, and characterized by feedback loops that make the system adaptive. Therefore, interventions in these systems are: ‘characterized by feedback loops, adaptation and learning by both those delivering and those receiving the intervention [...] They are both sensitive to starting conditions and outcomes tend to change, possibly significantly, over time. Complex interventions have multiple components which may act independently and interdependently’. Ling, T. (2012). *Evaluating complex and unfolding interventions in real time*. Evaluation, 18(1), 79–91. <https://doi.org/10.1177/1356389011429629>

Given the conceptual and, more importantly, practical need to draw some boundaries around the COVAX Facility and COVAX AMC to enable us to define the evaluand and its attributes, this strategy opts to frame the COVAX Facility and COVAX AMC as a two-system model, or a system with two domains: the 'complicated' domain, which might be considered 'COVAX Facility and COVAX AMC – the intervention' and the 'complex' domain, which might be considered 'COVAX Facility and COVAX AMC – outcomes in context'.

Figure 8 – Types of system within COVAX Facility and COVAX AMC



Introducing a two-domain evaluation object (evaluand) for the evaluation does have some implications, and there are pitfalls to both seeing everything as complicated and compartmentalizing complexity. Traditional evaluation approaches that rely on frequency or counterfactual frameworks⁷⁴ to establish cause and effect fail to take account of context, non-linearity and other features of complex systems, such as tipping points. But there are also problems with approaches that graft complexity-aware methods onto conventional ones to evaluate 'the complex bits' of programs. Epistemologically, problems arise from bolting together reductionist and holistic approaches⁷⁵ without acknowledging either (i) how this affects the construction of areas such as program theory and EQs or (ii) that complexity is central to the nature of the evaluand.

Our proposed evaluation design distinguishes between these domains and proposes methods that are appropriate for each within the evaluation modules: right things, right way, right results, and learning. This recognizes the importance of studying the influence of context on causality as part of a complexity-informed evaluation approach.

Selecting methods

The overall evaluation design should be complementary to the methods deployed under each module. As such, selecting the overall evaluation design is both a bottom-up and top-down prioritization process.

For Module 3, the choice of methods is challenging. With high-profile evaluations such as this, there is an understandable desire to use methods that can measure and make strong attribution claims for impacts. These types of claim are produced with reductive methods that rely on regularity frameworks or, more

⁷⁴ Stern, E. (2015). *Impact Evaluation. A Guide for Commissioners and Managers*. Bond. https://www.bond.org.uk/sites/default/files/resource-documents/impact_evaluation_guide_0515.pdf

⁷⁵ Ling, T. (2012). *Evaluating complex and unfolding interventions in real time*. *Evaluation*, 18 (1), 79–91. <https://doi.org/10.1177/1356389011429629>

commonly, counterfactual frameworks as the basis for causal inference. Establishing cause-and-effect linkage, or making a causal claim, may be achieved through four possible models:⁷⁶

- **Regularity frameworks** that statistically analyze the frequency of association between cause and effect.
- **Counterfactual frameworks** that determine the difference between two situations identical apart from the intervention in question. This is the basis for randomized control trials and quasi-experimental approaches.
- **Multiple causation** in combinations of causes that lead to effect are analyzed in configurational approaches, such as qualitative comparative analysis and contribution analysis.
- **Generative causation**, in which the mechanisms that cause effects are identified, for example through theory-based and realist approaches.

The first and second of these models depend on being able to manipulate the causal actors and control the context of intervention; the third and fourth are suited to situations, such as the COVAX Facility and COVAX AMC, where this control is not feasible and evaluators must depend on observation.

In using the term 'causality', it is important to be clear that this does not imply a linear or binary relationship between cause (intervention) and effect (impact). It is possible that the relationship between cause and effect may be:⁷⁷

- **Both necessary and sufficient:** the cause always leads to the intended effect and is the only way to achieve this.
- **Necessary but not sufficient:** the cause is a necessary precondition for intended effects but they will not be achieved with other factors.
- **Sufficient but not necessary:** the intervention is one way to arrive at the effect but there are other ways.
- **Neither necessary nor sufficient but a contributory cause:** the intervention is a vital part of a 'package' of causal factors that together are sufficient to produce the intended effect. However, on its own the program is neither sufficient nor always necessary – if, for example, other effective causal packages did not include the intervention of interest.

The concept of 'contributory cause' recognizes that effects may be produced by several causes at once, none of which might be necessary nor sufficient for impact on its own. Thus effects are a result of a 'causal package', which is the intervention plus other factors. The idea of 'causal packages' is most relevant in the impact evaluation of complex interventions, such as the COVAX Facility and COVAX AMC. The intervention is a contributory cause of the impact if:⁷⁸

- The causal package with the intervention was sufficient to bring about the impact, and
- The intervention was a necessary part of that causal package.

⁷⁶ Stern, E. (2015). *Impact Evaluation. A Guide for Commissioners and Managers*. Bond. https://www.bond.org.uk/sites/default/files/resource-documents/impact_evaluation_guide_0515.pdf

⁷⁷ Stern, E., Stame, N., Mayne, J., Forss, K., Davies, R. and Befani, B. (2012). *Broadening the Range of Designs and Methods for Impact Evaluations* (Working Paper 38). Department for International Development.

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/67427/design-method-impact-eval.pdf

⁷⁸ Stern, E. (2015). *Impact Evaluation A Guide for Commissioners and Managers*. Bond. https://www.bond.org.uk/sites/default/files/resource-documents/impact_evaluation_guide_0515.pdf

Contributory causality is relevant when it is likely when there is more than one possible cause, i.e. the intervention is just one part of a causal package. In complex systems the cause will seldom be the intervention – something done to the system – taken alone.

It should be noted that the evaluation approach should not overemphasize the causal question ‘did the intervention make a difference?’; equally important is the explanatory question ‘how did the intervention make a difference?’ The ‘how’ question gets to the heart of causal mechanism, and allows context to be examined – ‘when’, ‘where’, and for whom does the intervention work, ‘under what conditions?’⁷⁹

How context is dealt with is an important differentiator between different evaluation approaches. Experimental approaches conceive of contextual factors as confounding variables for which the evaluator should control. In theory-based approaches, interventions are considered to operate in interaction with context (people, policies, culture, etc.) and so context is key to understanding the interplay between programs and effects. Context is therefore considered to be part of the evaluation, as it is critical to uncovering the circumstances in which, and the reasons why, a particular intervention works. These approaches acknowledge that particular contexts can enhance or detract from program effectiveness and that such contexts may include factors that are within or outside the control of implementers.⁸⁰

It therefore follows that, in theory-based approaches and realistic evaluation, the impact of interventions cannot be determined with any degree of confidence if there is no knowledge about the context within which they have taken place. ‘An understanding of context is, therefore, vital in relation to attributing cause. Context is also seen as important in terms of replicating the intervention in any future setting or in learning about possible generalizable causal pathways’.⁸¹

In TBE, theory bridges causes and effects. The influential Stern paper on options for evaluation in international development⁸² identifies two types of TBE approach – process-oriented and mechanism-oriented – though it notes that these are usually inextricably interwoven (as it is proposed that they will be here). Process-oriented TBE follows various causal links in a chain of implementation of an intervention, ‘built around a “theory” that is a set of assumptions about how the intervention achieves its objectives and under what conditions’.⁸³ The most commonly used process-oriented TBE methods are contribution analysis and process tracing, and there are others, such as Participatory Impact Pathway Analysis,⁸⁴ that use impact pathway analysis.

In mechanism-based TBE, in order to make a causal claim, a mechanism that ‘makes things happen’ needs to be identified. But mechanisms do not operate in vacuums – the interaction with context is important. Mechanism-based TBE seeks the connection between causes and effects through deep theoretical analysis, based on mid-range theories.⁸⁵ This type of TBE stems from a ‘realist’ perspective, and its most common method is realist evaluation.⁸⁶

Case-based methods make systematic causal analysis of ‘cases’. The method most relevant to the COVAX Facility and COVAX AMC is Qualitative Comparative Analysis (QCA). This makes quantitative analysis, using

⁷⁹ Byrne, D. (2013). *Evaluating complex social interventions in a complex world*. Evaluation, 19 (3), 217–28. <https://doi.org/10.1177/1356389013495617>

⁸⁰ Blamey, A. and Mackenzie, M. (2007). *Theories of Change and Realistic Evaluation: Peas in a Pod or Apples and Oranges?* Evaluation, 13 (4), 439–55. <https://doi.org/10.1177/1356389007082129>

⁸¹ Ibid.

⁸² Stern, E., Stame, N., Mayne, J., Forss, K., Davies, R. and Befani, B. (2012). *Broadening the Range of Designs and Methods for Impact Evaluations* (Working Paper 38). Department for International Development. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/67427/design-method-impact-eval.pdf

⁸³ Ibid.

⁸⁴ Douthwaite, B., Kuby, T., van de Fliert, E. and Schulz, S. (2003). *Impact pathway evaluation: an approach for achieving and attributing impact in complex systems*. Agricultural Systems, 78 (2), 243–65. [https://doi.org/10.1016/S0308-521X\(03\)00128-8](https://doi.org/10.1016/S0308-521X(03)00128-8)

⁸⁵ Stern, E., Stame, N., Mayne, J., Forss, K., Davies, R., & Befani, B. (2012). *Broadening the Range of Designs and Methods for Impact Evaluations* (Working Paper 38). Department for International Development. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/67427/design-method-impact-eval.pdf

⁸⁶ Pawson, R. and Tilley, N. (1997). *Realistic Evaluation*. Sage.

fuzzy set logic, of ‘configurations’ of cases and their qualitative attributes to determine the conditions that are necessary and sufficient for an outcome to occur.

The suggested design for the COVAX Facility and COVAX AMC MSE is to use a blend of methods from the TBE family, particularly in relation to Modules 2 and 3.

Approach to learning

Our approach to learning is predominantly based on synthesizing and prioritizing lessons learned, gathered and documented through the earlier modules.

As noted above, the objective is to generate learning to inform course correction and transformative learning for future pandemic preparedness. Transformative learning theory is primarily aimed at encouraging arguments and world views to be questioned through a ‘disorienting dilemma’. The basic premise is that ‘disorientation’ will lead to a fundamental change in the way that we view the world. The evaluation team recognize that this ‘challenge’ function is particularly important in the context of the COVAX Facility and COVAX AMC evaluation. This is because (a) the MSE process spans a 10-year period, representing an important investment and opportunity to track the evolution of the Facility and AMC in response to pandemic evolution, and (b) the global health community needs answers to the macro-level question of how it can respond most effectively to plan for and respond to future pandemics or similar global health security threats. The evaluation approach has been designed to facilitate such learning in a number of ways:

- **Primary learning content focus:** We have set out the intention to focus learning from the formative review and baseline study on informing course correction for the COVAX Facility and COVAX AMC and Gavi 5.0. This is because it is the right time for this sort of learning and it will be of value now. Later evaluation processes will have a stronger emphasis on learning for future pandemic preparedness and response.
- **Evaluation approach and methodology:** The evaluation approach places a strong emphasis on understanding the context and how this has influenced design, implementation and results. This includes PEA to explore how power imbalances and political and economic concerns and incentives have influenced the design and implementation of the COVAX Facility and AMC, and also how these incentives have influenced SFP and AMC country decisions on whether and how to engage with COVAX. This analysis of context will provide a strong basis to challenge the status quo.
- **Data collection:** We have proposed a robust stakeholder engagement approach and data collection process to ensure that different world views are captured. This includes interviewing global experts, both within and outside of the COVAX architecture.
- **Evaluation team:** Our team includes a Technical Advisory Group of globally recognized experts that will advise the team throughout the evaluation. It will also include a well-respected and competent partner organization from the Global South to implement the evaluation that will also ensure that different world views are captured.
- **Stakeholder engagement:** Our approach includes a reflective and open validation processes (e.g. sense-making/learning and validation workshops with relevant stakeholder groups) to ensure that different world views are integrated within the development and finalization of recommendations.

In terms of ‘how’ synthesis and prioritization are done, we propose a continuous learning support approach during the formative review and baseline (and recommend this later, throughout the MSE). Our continuous learning approach aims to:

- synthesize learning across all evaluation activity;

- develop synthesis products that present learning from the evaluation;
- work collaboratively with and support the Office of the COVAX Facility/Gavi ELU continuous learning function; and
- facilitate uptake of lessons learned among key stakeholder groups for the MSE.

We identify three potential options providing different levels of support to the learning function administered by the Office of the COVAX Facility/Gavi ELU, as outlined below.

Table 18 - Options for levels of learning support

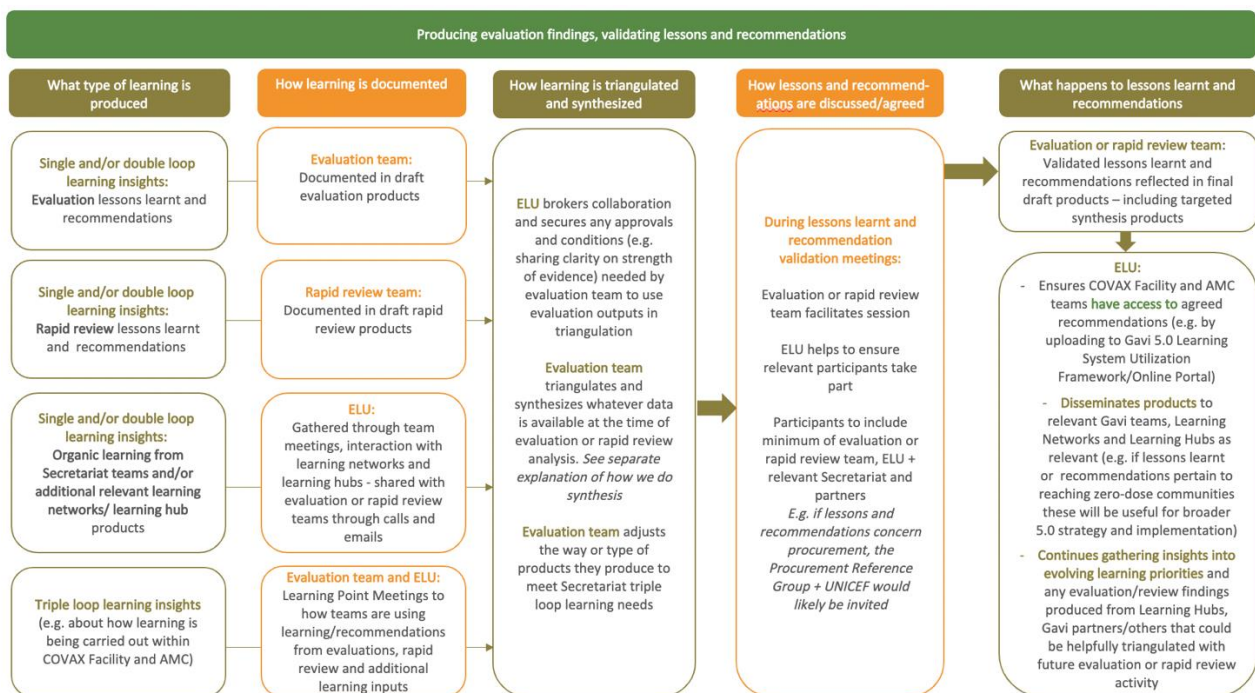
	Option 1: Light-touch learning support	Option 2: Mid-level learning support	Option 3: Semi-embedded learning support
Learning point meetings	Facilitate learning point meetings to: (a) revisit and agree upcoming learning priorities; (b) understand how learning generated through the MSE is being used to support decision making and course correction; (c) agree to any refinements needed in the way learning is presented within the MSE.	Per light-touch	Per light-touch
Documents and products	Synthesis of lessons learned arising from <i>formative/summative evaluations</i> and <i>rapid reviews</i> .	Per light-touch	Per light-touch
Workshops	Facilitation to support validation of lessons learned through sense-making workshops/ recommendation co-creation workshops with relevant teams.	Per light-touch	Per light-touch
Updating the COVAX Facility and COVAX AMC communications and learning plan	Following learning point meetings and evaluation activity synthesis. To ensure evolving learning priority and communication needs are captured.	Per light-touch	Per light-touch
Facilitating learning action sessions as required		At the end of each formative/summative evaluation and rapid review, facilitate a <i>learning action meeting</i> with key and relevant teams to help articulate the learning pathway action plan for recommendations, i.e. clarifying implications of the recommendations, what needs to happen, by whom and by when, etc.	Per mid-level
Coordination with Gavi Learning System learning hubs			At the end of each formative/summative evaluation and rapid review, the external evaluation learning lead contacts Gavi LS learning hubs to explore and facilitate sharing of any programmatic, equity-related, AMC country-related learning that can be used to inform hub's own learning and dissemination

We identify the following pros and cons for each option:

- **Light-touch learning support:** This is our recommended option. This option relies on the Office of the COVAX Facility/Gavi ELU leading on activity related to learning uptake of evaluation findings. This option affords the external evaluation team maximum independence, which is important to stakeholder groups, as we discovered through document review and KIIs.
- **Mid-level learning support:** This would provide a discrete amount of additional technical support to the learning function to support action/uptake of learning arising from evaluations and rapid reviews. While this option could help MEL and the wider Office of the COVAX Facility staff to operationalize recommendations, it could reduce the perception of evaluation team independence.
- **Semi-embedded learning support:** This would provide additional technical support to foster explicit linkage between the COVAX Facility and COVAX AMC MSE activity and the wider Gavi 5.0 Learning System learning hubs. This could help to promote cross-pollination of learning arising from formative review and baseline country work and potential for triangulation of learning from hubs related to country experiences. However, this option implies an even more reduced level of independence and could raise concern around potential conflict of interest.

Assuming a light-touch option is selected, a proposed approach to working alongside the ELU is set out in Figure 9 below.

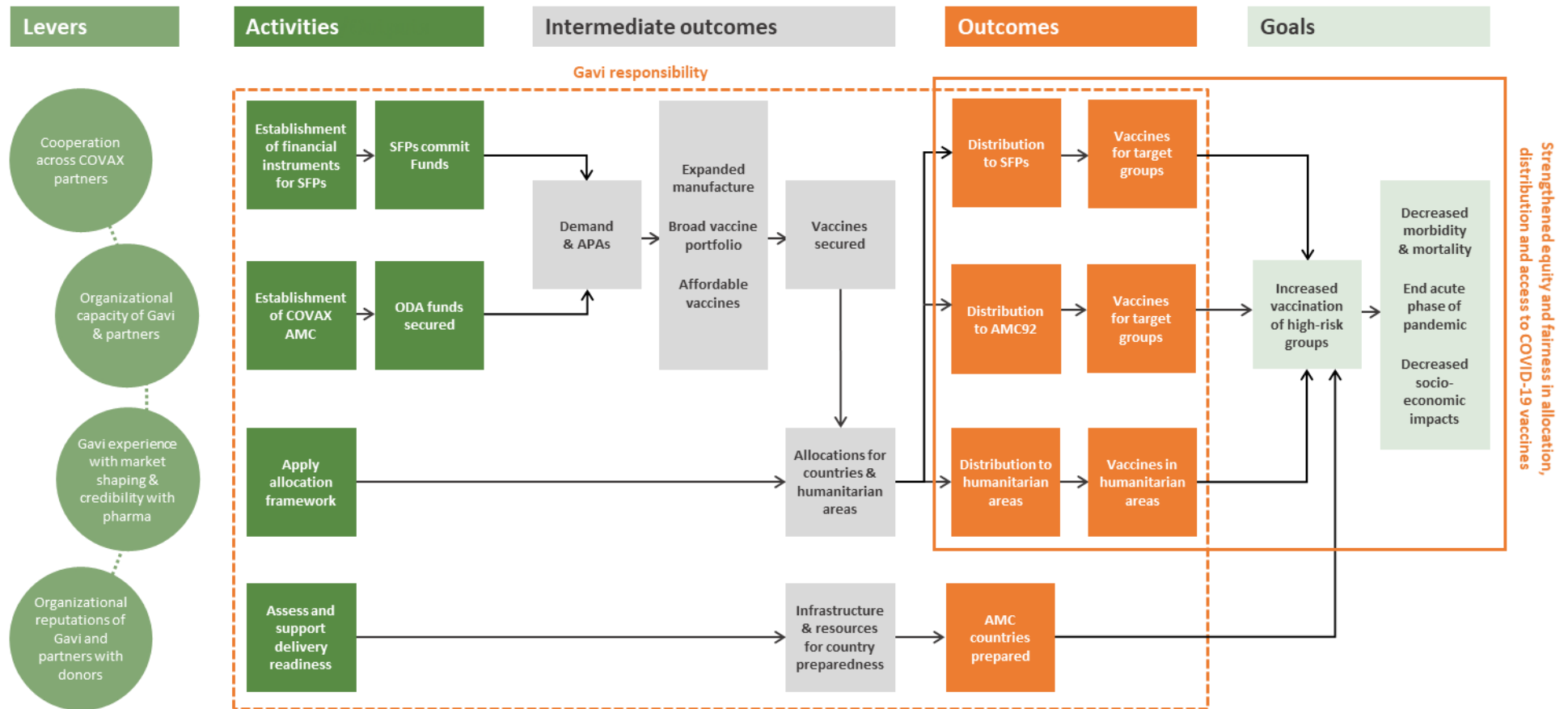
Figure 9 – Working alongside the ELU to produce evaluation findings, validate lessons and recommendations



Annex 8: Articulating the evaluation ToC for COVAX Facility and COVAX AMC

Building on the work conducted in the evaluability assessment and incorporating the existing ToC work, Figure 9 presents an updated articulation of the overall ToC for the COVAX Facility and COVAX AMC – referred to as the evaluation ToC.

Figure 10 - Updated ToC for the COVAX Facility and COVAX AMC



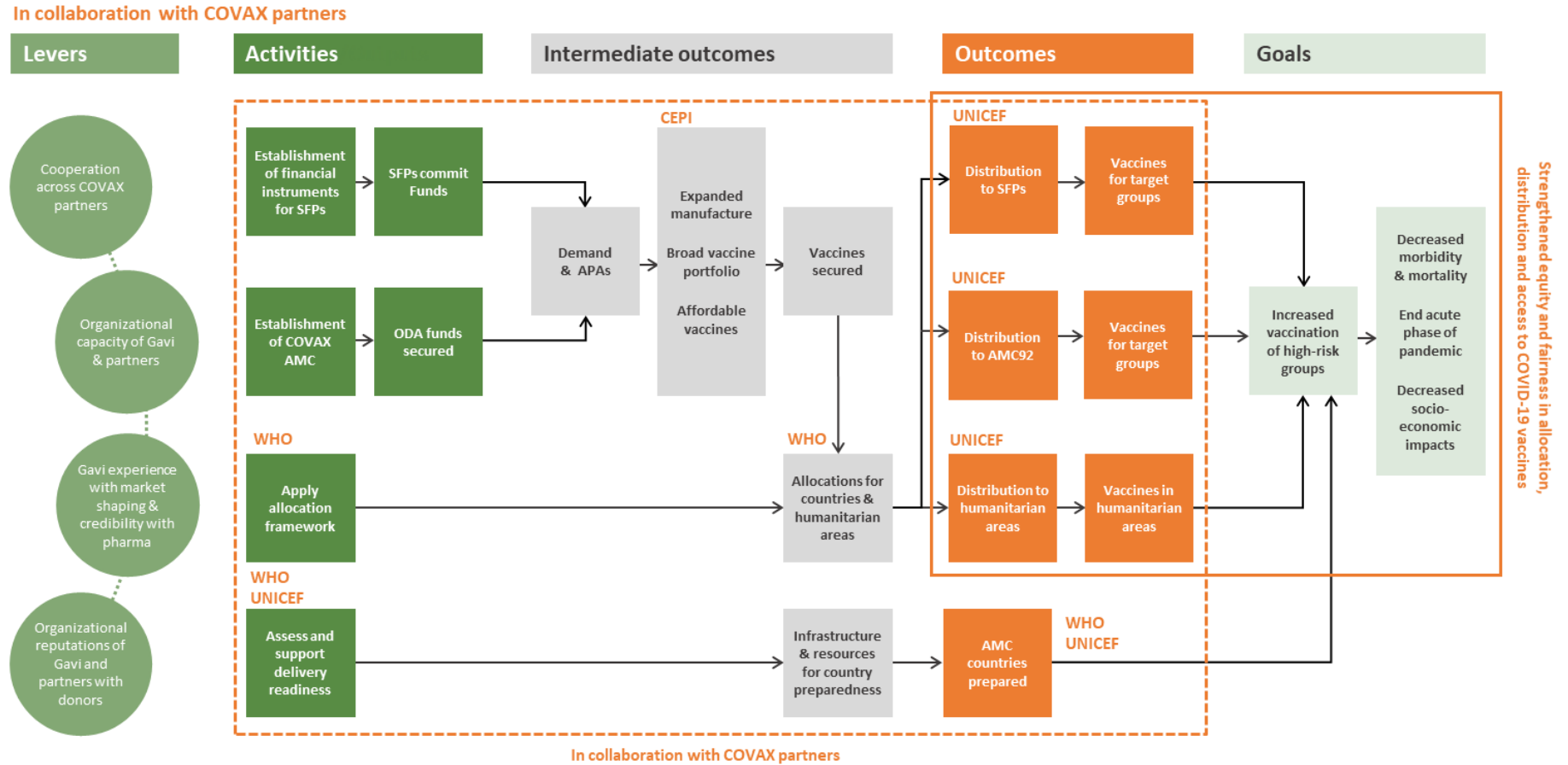
Evolving design. This ToC reflects the status quo as of late 2021, and recognizes the evolving nature of the design of the COVAX Facility and COVAX AMC, as it includes design revisions in the past 18 months of operation, in response to pandemic and geopolitical realities. There are ongoing discussions about design revisions needed for course correction, and indeed for the period 2022 onwards. The ToC for the COVAX Facility and COVAX AMC will need to be a living document, to be reviewed and revised as the evaluation proceeds.

Intervention logic. The ToC presents the core activities and outputs of the COVAX Facility and COVAX AMC, plus intermediate and higher-level outcomes. It also shows higher-level goals, i.e. health and socioeconomic change, to which the COVAX Facility and COVAX AMC contribute. Main programmatic activity areas of the COVAX Facility and COVAX AMC (each with their own, specific intervention logic, see below) evolve around: 1) engagement of *self-financing participants and AMC92 participants*, and joint procurement resulting in secured vaccine doses and a broad vaccine portfolio; 2) application of the equitable *vaccine allocation framework*, resulting in the most equitable and efficient allocation of secured doses; 3) *procurement and distribution of vaccine doses* to participants, resulting in availability of vaccine doses for the most at risk populations across and within countries; and 4) assessment of and support for *country-level vaccine delivery readiness* for AMC92 countries resulting in increased efficiency and effectiveness of vaccine delivery to high-risk populations.

Evidence and assumptions. The design of the COVAX Facility and COVAX AMC is based on prior experience of COVAX partners and evidence from earlier programs on large scale procurement and delivery of vaccines. That said, this is a novel initiative designed under time pressure, so various assumptions lie behind program components as well as causal links between activities and outcomes. Various assumptions have been identified by the Office of the COVAX Facility, Gavi Secretariat and partners, and articulated in project documents. The ToC provides a conceptual framework to clarify, identify additional and test assumptions as well as to gather evidence for causal links.

Collaborative effort. The ToC for the Facility and AMC is focused on the areas of Gavi's primary responsibility within the COVAX pillar but takes into account the roles and contributions of all COVAX partners, as well as other stakeholders. Although the Office of the COVAX Facility coordinates the implementation of the COVAX Facility and COVAX AMC, its success depends on all COVAX partners' contributions, including but not limited to 1) WHO's normative and technical support for equitable allocation and CRD; 2) UNICEF and PAHO's procurement and delivery of commodities, and 3) CEPI's work on incentivizing research, development and manufacturing of COVID-19 vaccines. The ToC will clarify roles and responsibilities, and interdependencies between COVAX partners' work, as they evolve, and clarify the scope of the multi-stage evaluation vis-à-vis evaluative work commissioned by partners around their efforts. The figure below (Figure 11) indicates the remit of Gavi's primary area of responsibility within the Facility and AMC, including key program areas with joint responsibilities.

Figure 11 - Collaborative components of the ToC for the COVAX Facility and COVAX AMC

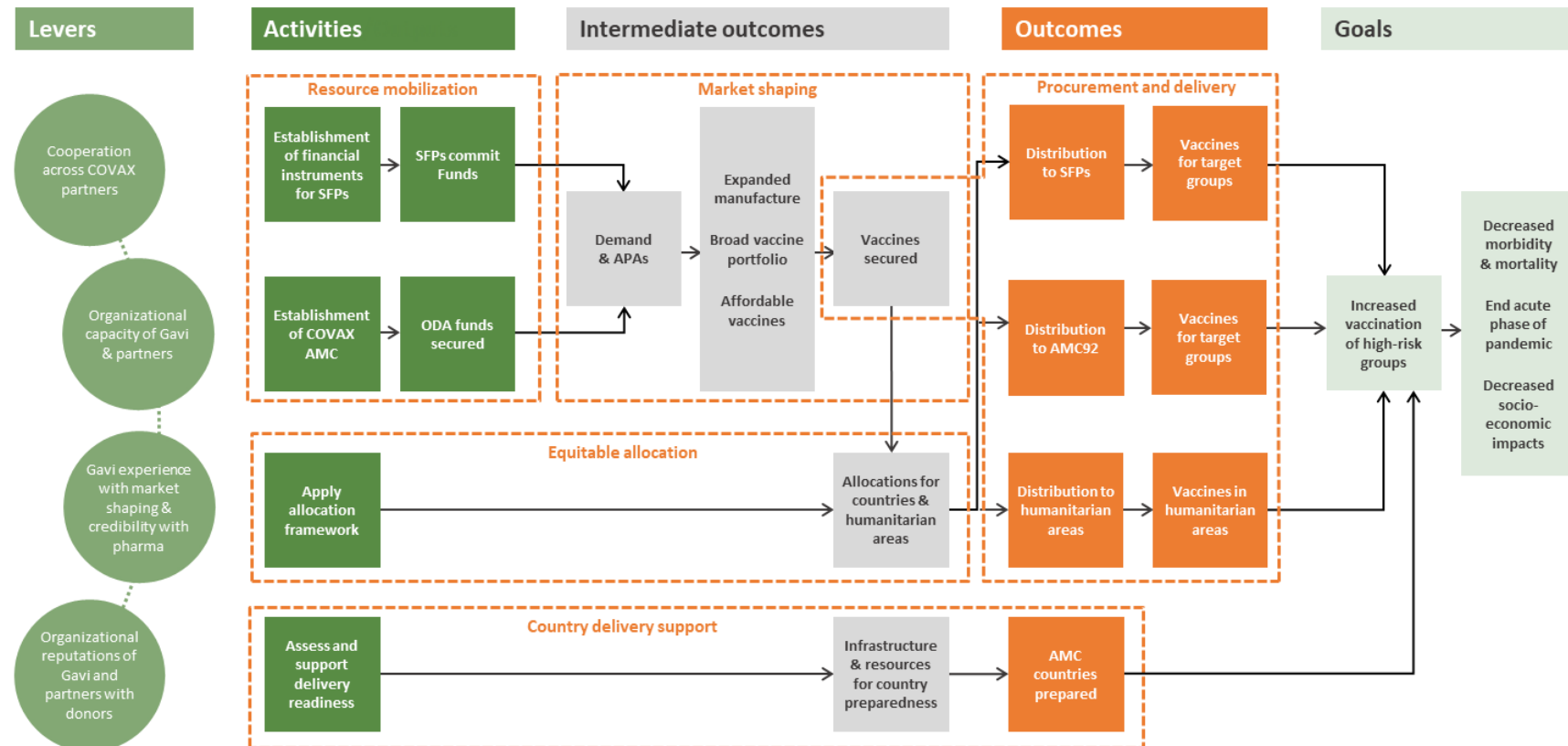


Guiding EQs. The ToC serves as the basis for the theory-based evaluation approach, as it guides EQs around assumptions and design options (right design), and testing the causal links between inputs and outputs (right way) and to outcomes and impact (right results). Also, as the ToC captures design revisions over time, it guides EQs through the evaluation approach about the geopolitical and epidemiological context, decision making processes and outcomes around the COVAX Facility and COVAX AMC.

Program areas within the COVAX Facility and COVAX AMC. The ToC helps clarify where specific program areas sit – see Figure 12. Clearly, the evaluation, and the core EQs, apply to the Facility and AMC as a whole, but also to specific program components. All COVAX Facility programmatic areas will be included in all stages of the formative-summative evaluations, albeit at varying degrees of intensity. Specific programmatic areas or strategies may be evaluated through additional rapid reviews, as the need arises, or at the recommendation of a formative-summative evaluation. Note that programmatic areas and specific strategies are not static; new programmatic areas may emerge and relative importance of various programmatic areas will change over time, for example country level delivery versus scaling up manufacturing.

Figure 12 – Programmatic areas within the COVAX Facility and COVAX AMC ToC

“Nested TOCs” for programme strategies



Annex 9: Data sources and descriptions

Table 19 - Relevant data sources

Data source	What	Relevance to EQ	Who	Reporting frequency	Notes
<u>COVAX Reporting Framework</u>	Topline performance metrics spanning inputs through to impact, mapped against COVAX core Theory of Change	2.2 – 2.2.5 3 – 3.5	Gavi Secretariat	Quarterly	Impact modelling still under development Complementary monitoring and reporting will also be of clear interest – e.g. the CRD Implementation Monitoring Review; COVID-19 Vaccine Delivery Support (CRD) monitoring data
WHO-UNICEF electronic Joint Reporting Form (eJRF) – COVID-19 module	Vaccination uptake (total) and disaggregated by gender, health workers, older adults and vulnerable people (co-morbidities, long-term care inhabitants)	3.2, 3.3, 3.4	WHO and UNICEF	Monthly	Reporting completeness is lacking/inconsistent Some regions are asking for differentiated data on COVAX vs non-COVAX doses; estimates are otherwise used (Gavi/WHO)
<u>WHO Officially Reported COVID-19 Vaccination Data</u>	By region and by country: Procured doses by vaccine type and procurement mechanism Vaccine uptake by per 100 population and by month Doses received and remaining Vaccinated by age group, target group and sex By region: Vaccine policy & Vaccine delivery strategy Acceptance and demand Wastage Supply management/cold chain	3.2, 3.3, 3.4	WHO	Daily	171 countries reported
National Vaccine Deployment Plans (NVDPs)	Operational measures per country to support: Regulatory preparedness Planning and coordination & Costing and budget Target populations and vaccination strategies Supply chain and healthcare waste management Human resources Vaccine acceptance and demand & Vaccine safety Immunization monitoring	3.2, 3.3	Country governments with input from WHO, UNICEF and partners	N/A	Some NVDPs currently available online – e.g. Sudan – but not all countries have published
<u>COVID-19 Vaccine Market Dashboard</u>	COVID-19 vaccine supply agreements by recipient Reported COVID-19 vaccine price per dose COVID-19 vaccine deliveries Immunization device overview	3.1, 3.2, 3.3, 3.4	UNICEF-run platform with data aggregated UNICEF and PAHO logistics data, and from other public sources, Our World in Data	Not known	
<u>WHO Coronavirus (COVID-19) Dashboard</u>	Confirmed COVID-19 cases and deaths (globally, regionally and nationally)	3.2, 3.4	World Health Organization	Daily (weekdays)	


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<u>IMF-WHO COVID-19 Vaccine Tracker</u>	No. vaccine doses secured by countries/regions through: bilateral agreements, donations, COVAX, World Bank, Asian Development Bank and other institutions	3.1, 3.4	IMF/WHO	Weekly
<u>Global Dashboard for Vaccine Equity</u>	Vaccine roll-out data combined with socioeconomic data – by country and L/M/H IC status; coverage status; cost of vaccination coverage as % of GDP	2.2.4, 3.1, 3.2	UNDP with data from UNICEF, IMF, WHO, COVAX, OWD and other sources	Unclear

Annex 10: Multi-stage evaluation framework

This table can be read in conjunction with Annex 16 (Table 24) which provides an overview of when different types of evaluation findings (i.e. findings on course correction, versus future pandemic preparedness) are likely to be produced, to meet different evaluation user needs anticipated.

Table 20 - Multi-stage evaluation framework


Evaluation module	EQ	Core EQs (Bold = headline EQ)	When	Stage-specific EQs			Primary users	Criteria for judging performance	Analytical methods	Data sources
				Formative review and baseline study	Mid-term	End-term				
 <p>1. Right things: Design</p>	1	Is the design and intervention logic underpinning the COVAX Facility and AMC clear, relevant, inclusive and appropriate to enable achievement of intended outcomes and impact?	<ul style="list-style-type: none"> Baseline Midterm End-term⁸⁷ 	Given the uncertain nature of the emerging pandemic, was the COVAX Facility and AMC design developed in an evidence based and coherent manner to maximize the chances for success?	What is the emerging evidence on whether and how the design is appropriate to facilitate progress towards results?	To what extent did the design facilitate the achievement of results?	<ul style="list-style-type: none"> Board & PPC Office of COVAX Facility COVAX implementing partners COVAX participants Wider global health community, including CSOs 	<ul style="list-style-type: none"> Design, evidence and assumptions clearly documented Options and trade-offs considered Strong and broad-based support for selected design Selected design coherent, well justified and in line with (a) COVAX principles, aims and strategies; and (b) global needs Evidence of design revisions in response to evidence of what works and evolving context 	<ul style="list-style-type: none"> ToC construction, incorporating history of decisions and timeline analysis Political economy analysis Benchmarking of design decisions against process criteria 	<ul style="list-style-type: none"> KIIs FGDs Document review Stakeholder workshops Web-survey Country case studies
	1.1	To what extent are the overall design of the COVAX Facility and AMC and specific strategies clearly justified and documented, and is the overall design clear and coherent?	<ul style="list-style-type: none"> Baseline Midterm End-term Rapid reviews 	To what extent is the overall design of the COVAX Facility and AMC and specific strategies clearly justified and documented, including the evidence base, and assumptions related to causal links between outcomes? Is the overall design clear and coherent?	To what extent is the overall design of the COVAX Facility and AMC and specific strategies, including any revisions, clearly justified and documented, including the evidence base, and assumptions related to causal links between outcomes? Is the overall design clear and coherent?	To what extent has the overall design of the COVAX Facility and AMC and specific strategies been clearly justified and documented, including the evidence base, and assumptions related to causal links between outcomes? Is the overall design clear and coherent?				
	1.2	Recognizing the dynamic nature of the pandemic and geopolitical context, what design revisions were made since the original design, and why?	<ul style="list-style-type: none"> Baseline Midterm End-term 	How has the design shifted over time based on the evolving pandemic and geopolitical context, and based on what justification and evidence?	How has the design shifted over time based on the evolving pandemic and geopolitical context, and based on what justification and evidence?	How has the design shifted over time based on the evolving pandemic and geopolitical context, and based on what justification and evidence?				

⁸⁷ Formative-summative evaluation work will assess overall design, whereas stage-specific EQs or rapid reviews may assess the relevance and coherence of specific program areas or strategies.

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1.3	How did external stakeholders and COVAX partners contribute to the original design, and subsequent design revisions of the COVAX Facility and AMC, and what impact did this have?	<ul style="list-style-type: none"> ▪ Baseline ▪ Midterm ▪ End-term 	How were external stakeholders and COVAX partners contribute to the original design of the COVAX Facility and AMC, and what impact did this have?	How have external stakeholders and COVAX partners contributed to design revisions over time, and what impact has this had?	How have external stakeholders and COVAX partners contributed to the COVAX Facility and AMC design, and what impact has this had?		<ul style="list-style-type: none"> ▪ Equity in design process (e.g. with transparency, consensus, stakeholder participation) ▪ Evidence of broad-based inputs influencing design ▪ Broad-based support for selected design 	<ul style="list-style-type: none"> ▪ Stakeholder analysis ▪ Political economy analysis 	
1.4	Are any design revisions needed for course correction? What are the design lessons for future pandemic responses?	<ul style="list-style-type: none"> ▪ Baseline ▪ Midterm ▪ End-term⁸⁸ ▪ Rapid reviews 	Are design revisions needed to inform course correction to facilitate short-term progress and results?	Are design revisions needed for course correction? Can emerging lessons inform future pandemic responses?	What are the design lessons for future pandemic responses?		<ul style="list-style-type: none"> ▪ Evidence that current design is sub-optimal for present context ▪ Alternative options, trade-offs and path dependencies analyzed and justified 	<ul style="list-style-type: none"> ▪ Synthesis of analysis and findings from other EQs 	

⁸⁸ The first part of the EQ will be asked at baseline and midterm, possibly also through rapid reviews. The second part will be asked at midterm and end-term, possibly also through rapid reviews.

Evaluation module	EQ	Core EQs (Bold = headline evaluation question)	When	Stage-specific EQs			Primary users	Criteria for judging performance	Analytical methods	Data sources
				Formative review and baseline study	Mid-term	End-term				
 <p>2. Right way: Implementation</p>	2	Have the COVAX Facility and AMC been successfully implemented?	<ul style="list-style-type: none"> Baseline Midterm End-term Rapid reviews 	Have the COVAX Facility and AMC been successfully set up and implemented thus far?	Have the COVAX Facility and AMC been successfully implemented to date?	Were the COVAX Facility and AMC implemented as intended?	<ul style="list-style-type: none"> Board & PPC Office of COVAX Facility + implementing partners COVAX participants Wider GH community 	<ul style="list-style-type: none"> Activities implemented in accordance with plans and expectations 	<ul style="list-style-type: none"> Synthesis of analysis and findings from EQs 2.1-2.2 	<ul style="list-style-type: none"> Document review KIIs/FGDs Web-survey Comparator case studies
	2.1	Have the COVAX Facility and AMC been operationalized successfully? (operational domain)	<ul style="list-style-type: none"> Baseline Midterm End-term Rapid reviews 	Are COVAX Facility and AMC operations suitable and appropriate, and been successfully set up and implemented thus far?	Have COVAX Facility and AMC operations been fit for purpose and successfully implemented to date?	Were COVAX Facility and AMC operations implemented as intended and how did this facilitate or impede the achievement of results?		<ul style="list-style-type: none"> COVAX Facility and AMC operations facilitate and enable implementation in accordance with plans and expectations 	<ul style="list-style-type: none"> Synthesis of analysis and findings from EQs 2.1.1-2.1.4 	
	2.1.1	Have the COVAX Facility and AMC management structures/governance arrangements been fit for purpose?	<ul style="list-style-type: none"> Baseline Midterm Rapid reviews 	Are the COVAX Facility and AMC management structures and governance arrangements suitable and appropriate for a new entity working in an emergency setting?	Have the COVAX Facility and AMC management structures and governance arrangements been well implemented and fit for purpose?	Was the COVAX Facility and AMC well managed and governed and to what extent did this facilitate or impede the achievement of results?	<ul style="list-style-type: none"> Board & PPC Office of COVAX Facility COVAX implementing partners 	<ul style="list-style-type: none"> The right capabilities, culture and practices are in place to enable implementation Agreed governance principles followed as intended 	<ul style="list-style-type: none"> Benchmarking to capability, culture and practice framework History of decisions and timeline analysis Process tracing Root cause analysis 	<ul style="list-style-type: none"> KIIs/FGDs Document review Web-survey
	2.1.2	Have the COVAX Facility and AMC risk management processes been fit for purpose?	<ul style="list-style-type: none"> Baseline Midterm End-term 	Are risk management systems, processes and capacities suitable and appropriate for dealing with the inherent risks associated with the COVAX Facility and AMC mandate?	Have the COVAX Facility and AMC risk management processes been well implemented and fit for purpose?	Were risk management processes appropriate and to what extent did this facilitate or impede the achievement of results?		<ul style="list-style-type: none"> Principles are in place to manage the effects of uncertainty on objectives Risk management is integrated into activities and functions Policies, procedures and practices are systematically applied Financial and programmatic risks are identified 	<ul style="list-style-type: none"> Risk management benchmark assessment Timeline analysis Comparator analysis (Gavi business as usual) Process tracing Root cause analysis 	<ul style="list-style-type: none"> Document review KIIs Comparator case studies


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								in a timely manner and mitigated		
	2.1.3	To what extent were the estimated costs of setting up and implementing the COVAX Facility and COVAX AMC in terms of finances and staff allocation reasonable and appropriate?	<ul style="list-style-type: none"> ▪ Baseline ▪ Midterm ▪ End-term ▪ Rapid reviews 	Were the initial set up costs for the COVAX Facility and AMC reasonable and appropriate for the organization mandate and proposed scale of operations?	To what extent are ongoing costs of implementing the COVAX Facility and COVAX AMC in terms of finances and staff allocation reasonable and appropriate?	To what extent were the estimated costs of setting up and implementing the COVAX Facility and COVAX AMC in terms of finances and staff allocation reasonable and appropriate?		<ul style="list-style-type: none"> ▪ Set-up costs are at or below relevant benchmarks 	<ul style="list-style-type: none"> ▪ Costing analysis for core processes ▪ Comparator analysis (Gavi Secretariat and other GHIs)) 	<ul style="list-style-type: none"> ▪ Document review ▪ KIIs/FGDs ▪ Comparator case studies
	2.1.4	Has the level of stakeholder engagement and communication been appropriate?	<ul style="list-style-type: none"> ▪ Baseline ▪ Midterm ▪ Rapid reviews 	How were external stakeholders and COVAX partners engaged in the early implementation of the COVAX Facility and AMC, and how did this guide decision making to support governance, management and implementation?	How have external stakeholders and COVAX partners engaged in the implementation of the COVAX Facility and AMC, and how has this been used guide decision making to support governance, management and implementation?	How have external stakeholders and COVAX partners contributed to decision making in support of governance, management and implementation, and what impact has this had?	<ul style="list-style-type: none"> ▪ Board & PPC ▪ Office of COVAX Facility + implementing partners ▪ COVAX participants ▪ Wider GH community 	<ul style="list-style-type: none"> ▪ Equity in decision making ▪ Governance and management arrangements support participation and engagement of all relevant stakeholders in key processes 	<ul style="list-style-type: none"> ▪ Stakeholder analysis ▪ Benchmarking to established standards ▪ Comparator analysis (Gavi business as usual) ▪ Process tracing ▪ Root cause analysis 	<ul style="list-style-type: none"> ▪ Document review ▪ KIIs/FGDs ▪ Stakeholder survey ▪ Comparator case studies

Evaluation module	EQ	Core EQs (Bold = headline evaluation question)	When	Stage-specific EQs			Primary users	Criteria for judging performance	Analytical methods	Data sources			
				Formative review and baseline study	Mid-term	End-term							
 <p>2. Right way: Implementation</p>	2.2	To what extent have the specific COVAX Facility and AMC programmatic/intervention areas been implemented successfully? (programmatic domain)	<ul style="list-style-type: none"> Baseline Midterm End-term Rapid reviews 	Have COVAX Facility and AMC programmatic areas been successfully set up and implemented thus far?	Have COVAX Facility and AMC programmatic areas been successfully implemented to date with expectations and targets met in a timely manner?	Were COVAX Facility and AMC programmatic areas implemented as intended, with expectations and targets met in a timely manner?	<ul style="list-style-type: none"> Board & PPC Office of COVAX Facility COVAX implementing partners COVAX participants Wider global health community, including CSOs 	<ul style="list-style-type: none"> COVAX Facility and COVAX AMC programmatic activities implemented in accordance with plans and expectations 	<ul style="list-style-type: none"> Synthesis of analysis and findings from other EQs 	<ul style="list-style-type: none"> Document review KIIs/FGDs Stakeholder workshops Web-survey Comparator case studies Country case studies Info systems 			
	2.2.1	To what extent has an appropriate resource mobilization strategy been established and implemented to secure adequate resources for full and timely implementation of intended activities?	<ul style="list-style-type: none"> Baseline Midterm End-term Rapid reviews 	Was a persuasive and appropriate resource mobilization strategy articulated to secure adequate resources for full and timely implementation of intended activities? To what extent were initial expectations and target met in a timely manner?	Has the resource mobilization strategy been well implemented, with expectations and targets met in a timely manner, to ensure ongoing delivery of the COVAX Facility and AMC ToC?	Were sufficient resources raised in a timely manner to secure adequate resources for full and timely implementation of intended activities?					<ul style="list-style-type: none"> Consensus amongst stakeholders on the strength of investment case Resources mobilized as planned/required to operationalize ToC Evidence of adaptation in response to evolving context 	<ul style="list-style-type: none"> Quantitative analysis of financial data Process tracing Root cause analysis 	
	2.2.2	To what extent have market shaping activities been implemented to ensure that COVID-19 vaccines are accessible and affordable for lower-income countries?	<ul style="list-style-type: none"> Baseline Midterm End-term Rapid reviews 	Was the market shaping approach adopted sufficiently powered and implemented to meet initial expectations on vaccine manufacturing and pricing?	Have market shaping activities been well implemented, with expectations and targets met in a timely manner, to ensure COVID-19 vaccines are accessible and affordable for lower-income countries?	Was the market shaping approach adopted and implemented sufficient to facilitate achievement of intended outcomes and impact?					<ul style="list-style-type: none"> Sufficient 'market power', tools and processes to influence supply and secure rapid access to adequate vaccines Demonstrated influence on supply and supply expansion Coordination with other stakeholders appropriate and adequate 	<ul style="list-style-type: none"> Process tracing Root cause analysis Comparator analysis (intro. of ART, and other Gavi/UNICEF market shaping efforts) 	<ul style="list-style-type: none"> Info systems Document review KIIs Web-survey Comparator case studies
	2.2.3	To what extent have the COVAX Facility and AMC supported procurement and delivery functions to ensure that COVID-19 vaccines are provided to	<ul style="list-style-type: none"> Baseline Midterm End-term Rapid reviews 	Was the role of the COVAX Facility and AMC clearly articulated, agreed and implemented to support procurement and delivery functions?	Has the role of the COVAX Facility and AMC sufficient been successfully implemented to support procurement and delivery	Was the role of the COVAX Facility and AMC sufficient and appropriate to support procurement and delivery functions, and provide					<ul style="list-style-type: none"> Roles and responsibilities well established Coordination with other stakeholders appropriate Adaptation in response to evolving context 	<ul style="list-style-type: none"> Process tracing Root cause analysis Country cross-case analysis Comparator analysis 	<ul style="list-style-type: none"> Info systems Document review KIIs Web-survey Country case studies


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	participants as planned?		How well has this worked to date?	functions, and provide COVID-19 vaccines to participants as planned?	COVID-19 vaccines to participants as planned?		<ul style="list-style-type: none"> ▪ Doses procured/purchased and shipped to delivery points in timely manner to meet targets/expectations 	(PAHO Revolving Fund, and Gavi/UNICEF business as usual)	<ul style="list-style-type: none"> ▪ Comparator case studies
2.2.4	To what extent have the COVAX Facility and AMC supported the operationalization of the allocation mechanism to ensure a fair and equitable distribution of COVID-19 vaccines?	<ul style="list-style-type: none"> ▪ Baseline ▪ Midterm ▪ Rapid reviews 	To what extent has the allocation mechanism design been reviewed, adjusted, and operationalized? Does this appear likely to ensure a fair and equitable distribution of COVID-19 vaccines?	How has the allocation mechanism been operationalized and modified, as needed, and what progress is being made to ensure a fair and equitable distribution of COVID-19 vaccines?	Has the allocation mechanism been successfully operationalized to ensure a fair and equitable distribution of COVID-19 vaccines?		<ul style="list-style-type: none"> ▪ Barriers and enablers to equitable allocation are widely communicated and understood ▪ Coordination between stakeholders appropriate ▪ Barriers to equitable allocation identified and addressed ▪ Equitable allocation, aligned to country needs and preference 	<ul style="list-style-type: none"> ▪ Process tracing ▪ Root cause analysis ▪ Country cross-case analysis ▪ Comparator analysis (PPE or C-19 treatments through ACT-A, and H1N1) 	<ul style="list-style-type: none"> ▪ KIIs/FGDs ▪ Web-survey ▪ Info systems ▪ Document review ▪ Country case studies
2.2.5	To what extent have the COVAX Facility and AMC supported CRD to facilitate the rollout of COVID-19 vaccines at the scale required to achieve intended outcomes and impact?	<ul style="list-style-type: none"> ▪ Baseline ▪ Midterm ▪ Rapid reviews 	Was the role of Gavi and the COVAX Facility and AMC vis-à-vis CRD clearly articulated, agreed and implemented in a timely manner?	To what extent has the COVAX Facility and AMC provided sufficient, timely and appropriate support to ensure CRD for the rollout of COVID-19 vaccines? Does this appear likely to facilitate achievement of intended outcomes and impact?	To what extent has the COVAX Facility and AMC's support for CRD enabled the rollout of COVID-19 vaccines and the achievement of intended outcomes and impact?		<ul style="list-style-type: none"> ▪ Barriers and enablers to CRD are understood ▪ CRD support systems and tools facilitate and enable TA and finance provision in accordance with plans and expectations ▪ CRD designed to add value and meet country needs 	<ul style="list-style-type: none"> ▪ Process tracing ▪ Root cause analysis ▪ Country cross-case analysis 	<ul style="list-style-type: none"> ▪ KIIs/FGDs ▪ Web-survey ▪ Information systems ▪ Document review ▪ Country case studies

Evaluation module	EQ	Core EQs (Bold = headline evaluation question)	When	Stage-specific EQs			Primary users	Criteria for judging performance	Analytical methods	Data sources									
				Formative review and baseline study	Mid-term	End-term													
 3. Right results: Outcomes and impact	3	To what extent have the COVAX Facility and AMC contributed to the achievement of intended outcomes and impact within the geopolitical and economic landscape?	<ul style="list-style-type: none"> Baseline Midterm End-term Rapid reviews 	What initial COVAX Facility and AMC results have been achieved and to what extent are intended outcomes and impacts on track to being achieved?	What results have been achieved to date and how has the COVAX Facility and AMC contributed to them within the global geopolitical and economic landscape? What are factors enabling and constraining success?	What results have been achieved, and how has the COVAX Facility and AMC contributed to them within the global geopolitical and economic landscape? What factors have enabled and/or constrained results?	<ul style="list-style-type: none"> Board & PPC Office of COVAX Facility COVAX implementing partners COVAX participants Wider global health community, including CSOs 	<ul style="list-style-type: none"> Intended results have been achieved, or are likely to be achieved in a timely manner Positive contribution to observed results vis-à-vis the role of others 	<ul style="list-style-type: none"> Verification of COVAX Reporting Framework indicator data Outward-in process tracing Root cause analysis 	<ul style="list-style-type: none"> KIIs/FGDs Document review Info systems Web-survey Country case studies 									
	3.1	To what extent have intended intermediate outcomes been achieved?	<ul style="list-style-type: none"> Baseline Midterm End-term Rapid reviews 	To what extent does the early emerging evidence suggest that intended intermediate outcomes across the programmatic areas of the ToC are likely to be achieved?	To what extent have intended intermediate outcomes been achieved at the mid-term, and are likely to be fully achieved by the end-term?	To what extent have intended intermediate outcomes been achieved?					<ul style="list-style-type: none"> Intended results have been achieved, or are likely to be achieved in a timely manner 	<ul style="list-style-type: none"> Outward-in process tracing Root cause analysis 	<ul style="list-style-type: none"> KIIs/FGDs Document review Info systems Web-survey Country case studies 						
	3.2	To what extent have the COVAX Facility and AMC intended outcomes and goals been achieved?	<ul style="list-style-type: none"> Midterm End-term Rapid reviews 	To what extent does the early emerging evidence suggest that intended outcomes and goals are likely to be achieved?	To what extent have intended outcomes and goals been achieved at the mid-term, and are likely to be fully achieved by the end-term?	To what extent have intended outcomes and goals been achieved?								<ul style="list-style-type: none"> Unintended consequences are understood and responded to 	<ul style="list-style-type: none"> Outward-in process tracing Root cause analysis Synthesis of findings to identify unintended consequences 	<ul style="list-style-type: none"> KIIs/FGDs Document review Info systems Web-survey Country case studies Survey 			
	3.3	What is the evidence to suggest that the COVAX Facility and AMC incurred unintended consequences and results beyond the ToC, and what were the implications?	<ul style="list-style-type: none"> Baseline Midterm End-term Rapid reviews 	What emerging evidence is there to suggest unintended consequences and results beyond the ToC?	What evidence is there to suggest unintended consequences and results beyond the ToC?	What were the unintended consequences and results beyond the ToC, and what were the implications?											<ul style="list-style-type: none"> Positive contribution to observed results vis-à-vis the role of others Reasons for strong / weak contribution are understood 	<ul style="list-style-type: none"> Contribution analysis 	<ul style="list-style-type: none"> KIIs/FGDs Document review Info systems Web-survey Country case studies
	3.4	How have the COVAX Facility and AMC contributed to achievement of outcomes and impacts within the global geopolitical and economic landscape?	<ul style="list-style-type: none"> Midterm End-term Rapid reviews 	To what extent does the early emerging evidence suggest that the COVAX Facility and AMC is likely to contribute to achievement of outcomes and impacts within the global geopolitical	To what extent has the COVAX Facility and AMC contributed, and is likely to continue, to achievement of outcomes and impacts within the global geopolitical	How have the COVAX Facility and AMC contributed to achievement of outcomes and impacts within the global geopolitical and economic landscape?													

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				and economic landscape?	and economic landscape of actors?					
	3.5	What are the most important barriers and enablers to achieving the outcomes and goals in the COVAX ToC at all levels of implementation?	<ul style="list-style-type: none"> Baseline Midterm End-term Rapid reviews 	What does the early emerging evidence suggest are barriers and enablers to achieving results?	What are the most important barriers and enablers to achieving the outcomes and goals in the COVAX ToC?	What were the most important barriers and enablers to achieving the outcomes and goals in the COVAX ToC?		<ul style="list-style-type: none"> Barriers and enablers are understood and responded to 	<ul style="list-style-type: none"> Synthesis of findings to identify barriers and enablers 	<ul style="list-style-type: none"> KIIs/FGDs Document review Info systems Web-survey Country case studies

Evaluation module	EQ #	EQs (Bold = headline evaluation question)	When	Stage-specific EQs			Primary users	Criteria for judging performance	Analytical methods	Data sources
				Formative review and baseline study	Mid-term evaluations	End-term evaluation				
 <p>4. Learning</p>		What lessons can be drawn from the design and implementation of the COVAX Facility and AMC?	<ul style="list-style-type: none"> Baseline Midterm End-term Rapid reviews 	What are the emerging lessons from the design and implementation of the COVAX Facility and COVAX AMC that have implications for course correction and Gavi 5.0?	What lessons can be drawn from the design and implementation of the COVAX Facility and COVAX AMC that have implications for course correction, Gavi 5.0, and future pandemic responses?	What lessons are there from the COVAX Facility and COVAX AMC that have implications for course correction, Gavi 5.0, and future pandemic responses?	<ul style="list-style-type: none"> Board & PPC Office of COVAX Facility COVAX implementing partners COVAX participants 	<ul style="list-style-type: none"> Lessons are generated, collated and disseminated Understanding of how lessons can be applied to COVAX Facility and COVAX AMC and/or other contexts understood 	<ul style="list-style-type: none"> Synthesis and prioritisation of lessons learned Sense-making workshops Country cross-case analysis 	<ul style="list-style-type: none"> KIIs/FGDs Document review Stakeholder workshops Web-survey
	4.1	What are the most important lessons learned through design and implementation experience that have implications for COVAX Facility and AMC course correction?	<ul style="list-style-type: none"> Baseline Midterm End-term Rapid reviews 	What are the emerging lessons from the design and implementation of the COVAX Facility and COVAX AMC that have implications for course correction?	What lessons can be drawn from the design and implementation of the COVAX Facility and COVAX AMC that have implications for course correction?	What lessons are there from the COVAX Facility and COVAX AMC that have implications for course correction?				
	4.2	What are the most important lessons learned through design and implementation experience that have implications for Gavi 5.0?	<ul style="list-style-type: none"> Midterm End-term Rapid reviews 	What are the emerging lessons from the design and implementation of the COVAX Facility and COVAX AMC that have	What lessons can be drawn from the design and implementation of the COVAX Facility and COVAX AMC that have implications for Gavi 5.0?	What lessons are there from the COVAX Facility and COVAX AMC that have implications for Gavi 5.0?				

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				implications for Gavi 5.0?						
	4.3	What are the most important lessons learned through design and implementation experience that have implications for future pandemic responses?	<ul style="list-style-type: none"> ▪ Midterm ▪ End-term ▪ Rapid reviews 	<i>This area is intentionally blank as the main focus of learning for this formative review and baseline is on more immediate COVAX course correction.</i>	What lessons can be drawn from the design and implementation of the COVAX Facility and COVAX AMC that have implications for future pandemic responses?	What lessons are there from the COVAX Facility and COVAX AMC that have implications for future pandemic responses?	<ul style="list-style-type: none"> ▪ Global health community 			
	4.4	What can be learned from other agencies/arrangements/context s and applied to the COVAX Facility and/or AMC for the achievement of intended outcomes and impact?	<ul style="list-style-type: none"> ▪ Baseline ▪ Midterm ▪ End-term ▪ Rapid reviews 	Which agencies, arrangements and contexts are most likely to provide useful learning for different aspects (design, operational, programmatic) of the COVAX Facility and COVAX AMC, and what can we learn from them?	What can be learned from other agencies/arrangements/context s and applied to the COVAX Facility and/or AMC for the achievement of outcomes and impact?	What lessons are there from the COVAX Facility and COVAX AMC and other agencies, arrangements and contexts for future pandemic response efforts?	<ul style="list-style-type: none"> ▪ Board & PPC ▪ Office of COVAX Facility ▪ COVAX implementing partners ▪ COVAX participants 			
	4.5	What can be learned from a comparison of countries' experiences of securing maximum possible vaccination supply and coverage, and applied to the COVAX Facility and/or AMC for the achievement of intended outcomes and impact?	<ul style="list-style-type: none"> ▪ Baseline ▪ Midterm ▪ End-term ▪ Rapid reviews 	What can be learned from an initial comparison of countries' experiences of securing maximum possible vaccination supply and coverage, and applied to the COVAX Facility and AMC for the achievement of outcomes and impact?	What can be learned from a comparison of countries' experiences of securing maximum possible vaccination supply and coverage, and applied to the COVAX Facility and AMC for the achievement of outcomes and impact?	What lessons are there from the COVAX Facility and COVAX AMC and countries' experiences of securing maximum possible vaccination supply and coverage for future pandemic response efforts?	<ul style="list-style-type: none"> ▪ Board & PPC ▪ Office of COVAX Facility ▪ COVAX implementing partners ▪ COVAX participants 			

Annex 11: Formative review and baseline study evaluation framework

Table 21 - Formative review and baseline study evaluation framework

EQ #	Stage-specific questions	Key issues for consideration	Primary users	Criteria for judging performance	Analytical methods	Data sources		
1	Given the uncertain nature of the emerging pandemic, was the COVAX Facility and AMC design developed in an evidence based and coherent manner to maximize the chances for success?	<ul style="list-style-type: none"> ▪ Design choices to be a global purchasing and allocation mechanism (including SFPs) ▪ Market shaping strategies employed ▪ Design of AMC ▪ Operationalizing the allocation mechanism based on principles of equity and fairness ▪ Relative balance between focus on scaling vaccine procurement and scaling country-level delivery 	<ul style="list-style-type: none"> ▪ Board & PPC ▪ Office of COVAX Facility ▪ COVAX implementing partners ▪ COVAX participants ▪ Wider global health community, including CSOs 	<ul style="list-style-type: none"> ▪ Design, evidence and assumptions clearly documented ▪ Options and trade-offs considered ▪ Strong and broad-based support for selected design ▪ Selected design coherent, well justified and in line with (a) COVAX principles, aims and strategies; and (b) global needs ▪ Evidence of design revisions in response to evidence of what works and evolving context 	<ul style="list-style-type: none"> ▪ ToC construction, incorporating history of decisions and timeline analysis ▪ Political economy analysis ▪ Benchmarking of design decisions against process criteria 	<ul style="list-style-type: none"> ▪ KIIs ▪ FGDs ▪ Document review ▪ Stakeholder workshops ▪ Web-survey ▪ Country case studies 		
1.1	To what extent is the overall design of the COVAX Facility and AMC and specific strategies clearly justified and documented, including the evidence base, and assumptions related to causal links between outcomes? Is the overall design clear and coherent?	<ul style="list-style-type: none"> ▪ ToC and intervention logic evidence base and assumptions ▪ Problem/context analysis, recognizing dynamic market, geopolitical and epidemiological context ▪ Alignment to COVAX vaccine pillar and ACT-A ▪ Roles, responsibilities and ways of working between organizations ▪ Other strategic options and trade-offs considered and documented 						
1.2	How has the design shifted over time based on the evolving pandemic and geopolitical context, and based on what justification and evidence?	<ul style="list-style-type: none"> ▪ Articulation of prevailing context ▪ Mapping of adaptation and modification to ToC, and justification provided, including evidence base and assumptions ▪ Other strategic options and trade-offs considered and documented 						
1.3	How were external stakeholders and COVAX partners contribute to the original design of the COVAX Facility and AMC, and what impact did this have?	<ul style="list-style-type: none"> ▪ Mapping of key stakeholders by programmatic area ▪ Power asymmetries between stakeholders ▪ Identification of opportunity for meaningful engagement by different constituency groups 					<ul style="list-style-type: none"> ▪ Equity in design process ▪ Evidence of broad-based inputs influencing design ▪ Broad-based support for selected design 	<ul style="list-style-type: none"> ▪ Stakeholder analysis ▪ Political economy analysis
1.4	Are design revisions needed to inform course correction to facilitate short-term progress and results?	<ul style="list-style-type: none"> ▪ Alternative strategic options and trade-offs ▪ 'Path dependencies' for design revisions to be successful 					<ul style="list-style-type: none"> ▪ Evidence that current design is sub-optimal for present context ▪ Alternative options, trade-offs and path dependencies analyzed and justified 	<ul style="list-style-type: none"> ▪ Synthesis of analysis and findings from other EQs

EQ #	Stage-specific questions	Key issues for consideration	Primary users	Criteria for judging performance	Analytical methods	Data sources
2	Have the COVAX Facility and AMC been successfully set up and implemented thus far?	Synthesis of operational and programmatic issues analyzed through sub-questions below		<ul style="list-style-type: none"> Activities implemented in accordance with plans and expectations 	<ul style="list-style-type: none"> Synthesis of analysis and findings from EQs 2.1–2.2 	<ul style="list-style-type: none"> Document review KIIs/FGDs Web-survey Comparator case studies
2.1	Are COVAX Facility and AMC operations suitable and appropriate, and been successfully set up and implemented thus far?	Synthesis of operational issues analyzed through sub-questions below				
2.1.1	Are the COVAX Facility and AMC management structures and governance arrangements suitable and appropriate for a new entity working in an emergency setting?	<ul style="list-style-type: none"> Evolution of management and governance structures Whether and how management structures and governance arrangements have enabled or hampered programmatic implementation and results Staff availability and working conditions 		<ul style="list-style-type: none"> The right capabilities, culture and practices are in place to enable implementation Agreed governance principles followed as intended 	<ul style="list-style-type: none"> Benchmarking to capability, culture and practice framework History of decisions and timeline analysis Process tracing Root cause analysis 	<ul style="list-style-type: none"> KIIs/FGDs Document review Web-survey
2.1.2	Are risk management systems, processes and capacities suitable and appropriate for dealing with the inherent risks associated with the COVAX Facility and AMC mandate?	<ul style="list-style-type: none"> Level of risk assumed by Gavi on behalf of COVAX Identification and mitigation of financial and programmatic challenges and risks Whether and how risk management has enabled or hampered programmatic implementation and results 	<ul style="list-style-type: none"> Board & PPC Office of COVAX Facility COVAX implementing partners COVAX participants Wider global health community, including CSOs 	<ul style="list-style-type: none"> Principles are in place to manage the effects of uncertainty on objectives Risk management is integrated into activities and functions Policies, procedures and practices are systematically applied Financial and programmatic risks are identified in a timely manner and mitigated 	<ul style="list-style-type: none"> Risk management benchmark assessment Timeline analysis Comparator analysis (Gavi business as usual) Process tracing Root cause analysis 	<ul style="list-style-type: none"> Document review KIIs Comparator case studies
2.1.3	Were the initial set up costs for the COVAX Facility and AMC reasonable and appropriate for the organization mandate and proposed scale of operations?	<ul style="list-style-type: none"> Costs incurred by Gavi in set up of COVAX Facility and AMC 		<ul style="list-style-type: none"> Set-up costs are at or below relevant benchmarks 	<ul style="list-style-type: none"> Costing analysis for core processes Comparator analysis (Gavi Secretariat and other GHIs) 	<ul style="list-style-type: none"> Document review KIIs/FGDs Comparator case studies
2.1.4	How were external stakeholders and COVAX partners engaged in the early implementation of the COVAX Facility and AMC, and how did this guide decision making to support governance, management and implementation?	<ul style="list-style-type: none"> Presence and implementation of stakeholder engagement plan Processes to ensure coherence and co-ordination across partners (e.g. within COVAX, other ACT A pillars, HSRC, IFIs and regional organizations and mechanisms) Whether and how stakeholder engagement enabled or hampered programmatic implementation and results 		<ul style="list-style-type: none"> Equity in decision making Governance and management arrangements support participation and engagement of all relevant stakeholders in key processes 	<ul style="list-style-type: none"> Stakeholder analysis Benchmarking to established standards Comparator analysis (Gavi business as usual) Process tracing Root cause analysis 	<ul style="list-style-type: none"> Document review KIIs/FGDs Stakeholder survey Comparator case studies

EQ #	Stage-specific questions	Key issues for consideration	Primary users	Criteria for judging performance	Analytical methods	Data sources
2.2	Have COVAX Facility and AMC programmatic areas been successfully set up and implemented thus far?	<ul style="list-style-type: none"> ▪ Synthesis of programmatic issues analyzed through sub-questions below ▪ For all sub-questions, consideration of the respective roles and contributions of all COVAX implementing partners to implementation 	<ul style="list-style-type: none"> ▪ Board & PPC ▪ Office of COVAX Facility ▪ COVAX implementing partners ▪ COVAX participants ▪ Wider global health community 	<ul style="list-style-type: none"> ▪ Activities implemented in accordance with plans and expectations 	<ul style="list-style-type: none"> ▪ Synthesis of analysis/findings from other EQs 	<ul style="list-style-type: none"> ▪ Document review ▪ KIIs/FGDs ▪ Stakeholder workshops
2.2.1	Was a persuasive and appropriate resource mobilization strategy articulated to secure adequate resources for full and timely implementation of intended activities? To what extent were initial expectations and targets met in a timely manner?	<ul style="list-style-type: none"> ▪ Presence of investment case ▪ Use of innovative financing mechanisms ▪ Sufficiency of resources mobilized to allow for the ToC to be operationalized as intended and in a timely manner ▪ Evolution of strategy in response to context (e.g. collaboration with World Bank, incorporating donations, cost-sharing for procurement and in-country delivery, and the emergence of new procurement platforms such as AVAT) 		<ul style="list-style-type: none"> ▪ Consensus amongst stakeholders on strength of investment case ▪ Resources mobilized as planned/required to operationalize the ToC ▪ Evidence of adaptation in response to evolving context 	<ul style="list-style-type: none"> ▪ Quantitative analysis of financial data ▪ Process tracing ▪ Root cause analysis 	<ul style="list-style-type: none"> ▪ Web-survey ▪ Comparator case studies ▪ Country case studies ▪ Info systems
2.2.2	Was the market shaping approach adopted sufficiently powered and implemented to meet initial expectations on vaccine manufacturing and pricing, and to secure supply?	<ul style="list-style-type: none"> ▪ Presence of systems, processes, capacities and tools to deliver market shaping objectives ▪ Contextual barriers or enablers to the involvement and influence of the COVAX Facility and AMC in market shaping ▪ Strengths and weaknesses of APAs to achieve the desired outcomes given the changing landscape ▪ Trade-offs between the range of market objectives ▪ Coordination/communication with participants ▪ Implementation course-corrections required 	<ul style="list-style-type: none"> ▪ COVAX implementing partners ▪ COVAX participants ▪ Wider global health community 	<ul style="list-style-type: none"> ▪ Sufficient 'market power', tools and processes to influence supply and secure access vaccines ▪ Influence on supply ▪ Coordination with other stakeholders appropriate and adequate 	<ul style="list-style-type: none"> ▪ Process tracing ▪ Root cause analysis ▪ Comparator analysis (intro. of ART, and other Gavi/UNICEF market shaping efforts) 	<ul style="list-style-type: none"> ▪ Info systems ▪ Document review ▪ KIIs ▪ Web-survey ▪ Comparator case studies
2.2.3	Was the role of the COVAX Facility and AMC clearly articulated, agreed and implemented to support procurement and delivery functions? How well has this worked to date?	<ul style="list-style-type: none"> ▪ Clarity of roles and responsibilities ▪ Approaches used to coordinate with other partners ▪ Evolution of procurement and delivery processes to respond to the changing context and needs (e.g. managing donations, humanitarian buffer, SFPs) ▪ Processes to coordinate between securing APAs and the later stages of procurement and delivery of doses 	<ul style="list-style-type: none"> ▪ COVAX implementing partners ▪ COVAX participants ▪ Wider global health community 	<ul style="list-style-type: none"> ▪ Roles and responsibilities well established ▪ Coordination with other stakeholders appropriate ▪ Adaptation in response to evolving context ▪ Doses procured/purchased and shipped to delivery points in timely manner to meet targets/expectations 	<ul style="list-style-type: none"> ▪ Process tracing ▪ Root cause analysis ▪ Country cross-case analysis ▪ Comparator analysis (PAHO Revolving Fund, and Gavi/UNICEF business as usual) 	<ul style="list-style-type: none"> ▪ Info systems ▪ Document review ▪ KIIs ▪ Web-survey ▪ Country case studies ▪ Comparator case studies
2.2.4	To what extent has the allocation mechanism design been reviewed, adjusted, and operationalized? Does this appear likely to ensure a fair and equitable distribution of COVID-19 vaccines?	<ul style="list-style-type: none"> ▪ Stakeholder engagement ▪ Coordination with partners to operationalize the allocation approach ▪ Distribution of volumes consistent with the allocation mechanism ▪ Alignment of vaccine distribution to country needs and preferences (e.g. presentation, expiry date) ▪ Alternative options and trade-offs 	<ul style="list-style-type: none"> ▪ Board & PPC ▪ Office of COVAX Facility ▪ COVAX implementing partners and participants ▪ Wider GH community 	<ul style="list-style-type: none"> ▪ Barriers and enablers to equitable allocation are widely communicated and understood ▪ Coordination between stakeholders appropriate ▪ Barriers to equitable allocation identified and addressed 	<ul style="list-style-type: none"> ▪ Process tracing ▪ Root cause analysis ▪ Country cross-case analysis ▪ Comparator analysis (PPE or C-19 treatments through ACT-A, and H1N1) 	<ul style="list-style-type: none"> ▪ KIIs/FGDs ▪ Web-survey ▪ Info systems ▪ Document review ▪ Country case studies

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				<ul style="list-style-type: none"> Equitable allocation, aligned to country needs and preference 		
2.2.5	Was the role of Gavi and the COVAX Facility and AMC vis-à-vis CRD clearly articulated, agreed and implemented in a timely manner?	<ul style="list-style-type: none"> Prioritization of CRD vis-à-vis other programmatic areas over time Presence of systems, processes and capacities to assess and support CRD, including country readiness assessments Coordination with stakeholders for achievement of joint results Country comms on vaccine availability and allocation decisions Alignment of TA and sufficiency of resource envelope to meet country needs Presence of feedback loops to identify and address lessons learned and adapt ways of working Timeliness of disbursements 	<ul style="list-style-type: none"> Board & PPC Gavi Sec + Office of COVAX Facility COVAX implementing partners and participants Wider GH community 	<ul style="list-style-type: none"> Barriers and enablers to CRD are understood CRD support systems and tools facilitate and enable TA and finance provision in accordance with plans and expectations CRD designed to add value and meet country needs 	<ul style="list-style-type: none"> Process tracing Root cause analysis Country cross-case analysis 	<ul style="list-style-type: none"> KIIs/FGDs Web-survey Information systems Document review Country case studies

EQ #	Stage-specific questions	Key issues for consideration	Primary users	Criteria for judging performance	Analytical methods	Data sources
3	What initial COVAX Facility and AMC results have been achieved and to what extent are intended outcomes and impacts on track to being achieved?	<ul style="list-style-type: none"> Synthesis of issues analyzed through sub-questions below Analysis of global geopolitical and economic landscape of actors involved in the delivery of COVID-19 vaccines 				
3.1	To what extent does the early emerging evidence suggest that intended intermediate outcomes across the programmatic areas of the ToC are likely to be achieved?	<ul style="list-style-type: none"> Verification and triangulation of Monitoring and Reporting Framework data on intermediate outcomes across the programmatic areas of the ToC (i.e. market shaping, procurement and delivery, equitable allocation and CRD) 	<ul style="list-style-type: none"> Board & PPC Office of COVAX Facility COVAX implementing partners COVAX participants Wider global health community, including CSOs 	<ul style="list-style-type: none"> Intended results have been achieved, or are likely to be achieved in a timely manner 	<ul style="list-style-type: none"> Verification of COVAX Reporting Framework indicator data Outward-in process tracing Root cause analysis 	<ul style="list-style-type: none"> KIIs/FGDs Document review Info systems Web-survey Country case studies
3.2	To what extent does the early emerging evidence suggest that intended outcomes and goals are likely to be achieved?	<ul style="list-style-type: none"> Verification and triangulation of Monitoring and Reporting Framework data on outcomes and goals, including 1) delivery to countries, 2) number of persons vaccinated, 3) equitable access 				
3.3	What emerging evidence is there to suggest unintended consequences and results beyond the ToC?	<ul style="list-style-type: none"> Effects of the COVAX Facility and AMC on routine immunization efforts? Other unintended consequences and results 		<ul style="list-style-type: none"> Unintended consequences are understood and responded to 	<ul style="list-style-type: none"> Outward-in process tracing Root cause analysis Synthesis of findings to identify unintended consequences 	<ul style="list-style-type: none"> KIIs/FGDs Document review Info systems Web-survey Country case studies Survey
3.4	To what extent does the early emerging evidence suggest that the COVAX Facility and AMC is likely to contribute to achievement of outcomes and impacts within the global	<ul style="list-style-type: none"> Consideration of the role of Gavi and Office of the COVAX Facility vis-à-vis other COVAX implementing partners and stakeholders working for the achievement of common outcomes and impact 		<ul style="list-style-type: none"> Positive intermediate outcomes in countries securing supply from COVAX 	<ul style="list-style-type: none"> Contribution analysis 	<ul style="list-style-type: none"> KIIs/FGDs Document review Info systems Web-survey

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	geopolitical and economic landscape?			<ul style="list-style-type: none"> Evidence of COVAX Facility and COVAX AMC contribution to outcomes 		<ul style="list-style-type: none"> Country case studies
3.5	What does the early emerging evidence suggest are barriers and enablers to achieving results?	<ul style="list-style-type: none"> Review and synthesis of barriers and enablers identified through literature and in conducting the formative review and baseline study 		<ul style="list-style-type: none"> Barriers and enablers are understood and responded to 	<ul style="list-style-type: none"> Synthesis of findings to identify barriers and enablers 	<ul style="list-style-type: none"> KIIs/FGDs Document review Info systems Web-survey Country case studies

EQ #	Stage-specific questions	Key issues for consideration	Primary users	Criteria for judging performance	Analytical methods	Data sources
4	What are the emerging lessons from the design and implementation of the COVAX Facility and COVAX AMC that have implications for course correction and Gavi 5.0?	Synthesis and prioritization of lessons learned	<ul style="list-style-type: none"> Board & PPC Office of COVAX Facility COVAX implementing partners COVAX participants 	<ul style="list-style-type: none"> Lessons are generated, collated and disseminated Understanding of how lessons can be applied to COVAX Facility and COVAX AMC and/or other contexts understood 	<ul style="list-style-type: none"> Synthesis and prioritization of lessons learned Sense-making workshops Country cross-case analysis 	<ul style="list-style-type: none"> KIIs/FGDs Document review Stakeholder workshops Web-survey
4.1	What are the emerging lessons from the design and implementation of the COVAX Facility and COVAX AMC that have implications for course correction?	<ul style="list-style-type: none"> Specific areas for learning are posed in Section 4.1.6 and Annex 16 				
4.2	What are the emerging lessons from the design and implementation of the COVAX Facility and COVAX AMC that have implications for Gavi 5.0?	<ul style="list-style-type: none"> Specific areas for learning are posed in Section 4.1.6 and Annex 16 	Board & PPC			
4.4	Which agencies, arrangements and contexts are most likely to provide useful learning for different aspects (design, operational, programmatic) of the COVAX Facility and COVAX AMC, and what can we learn from them?	<ul style="list-style-type: none"> Review and synthesis of learning generated from comparator analyses conducted across formative review and baseline study 	<ul style="list-style-type: none"> Board & PPC Office of COVAX Facility COVAX implementing partners and participants 			
4.5	What can be learned from an initial comparison of countries' experiences of securing maximum possible vaccination supply and coverage, and applied to the COVAX Facility and AMC for the achievement of outcomes and impact?	<ul style="list-style-type: none"> Identification of outliers from cross-country portfolio analysis Analysis of underlying reasons for observed differences, including how countries across the income spectrum have responded to the realities of sourcing vaccines differently, and which agencies and/or arrangements each has drawn down on, or not, and why 	<ul style="list-style-type: none"> Board & PPC Office of COVAX Facility COVAX implementing partners and participants 			

Annex 12: Analytical methods per evaluation module

A. Right things

ToC construction and history of decisions analysis

Each stage of the evaluation will start with an update of any revisions in overall and/or specific design since the last assessment. A comprehensive ToC will be constructed in a stakeholder workshop during the formative review and baseline study, including nested ToCs for program areas, assumptions and evidence base. Recognizing the responsiveness of the COVAX Facility and AMC design to an evolving context, every subsequent formative-summative evaluation exercise will include a ToC assessment and update, evaluating the relevance and coherence of design choices made in the interim, including the content and decision-making process of any revision.

Political Economy Analysis

We propose to use PEA as a tool to identify the political dimensions of designing and operationalizing the COVAX Facility and COVAX AMC, and to analyze the appropriateness of the selected design within the context of the incentives, relationships, and distribution and contestation of power between the different stakeholders engaged and with interests in its design and operationalization.⁸⁹ The PEA will draw upon *stakeholder analysis* conducted within the formative review and baseline study to map the level of stakeholder influence against their alignment with COVAX principles, aims or strategies (e.g. urgency, equal access globally, joint procurement) and *timeline analysis* to generate a clear understanding of the specific contexts in which stakeholders were acting.

Benchmarking design revisions

To further the analysis of appropriateness, we propose to assess or benchmark the process of decision revisions against a set of criteria. This would seek to understand if/how equity and other considerations were inbuilt in the design revision process. The selected criteria could usefully be drawn from existing 'Benchmarks of fairness'⁹⁰ and 'Accountability for reasonableness'⁹¹ frameworks to include criteria such as 'transparency', 'consensus' and 'stakeholder participation'. Others will likely be applicable and could be agreed at the outset of the formative review and baseline study.

B. Right way

Evaluation approaches for EQs in the operational domain are as follows:

Benchmarking

A benchmark – what 'good' looked like – will be established through the use of best practice frameworks, norms and standards, adjusted to account for the unprecedented context in which COVAX was operating. This will provide a basis against which to assess (a) if the right systems, processes and resources were in place to implement the ToC as intended, in the prevailing context; and (b) the appropriateness of decision making over time. Drawing on a document review, comparator case studies and KIIs, predominantly at

⁸⁹ Mcloughlin, C. (2014). *Political Economy Analysis: Topic Guide (2nd Ed.)*. Governance and Social Development Resource Centre. <https://gsdrc.org/wp-content/uploads/2015/07/PEA.pdf>

⁹⁰ Developed by Daniels and Caplan as a policy tool to generate discussion on trade-offs in health policy. Daniels N., Light, D.W. and Caplan, R. L. (1996). *Benchmarks of Fairness for Health Care Reform*. Oxford University Press; Caplan, R. L., Light, D. W., & Daniels, N. (1999). *Benchmarks of Fairness: A Moral Framework for Assessing Equity*. International Journal of Health Services, 29 (4), 853–69. <https://doi.org/10.2190/DBBU-WUCA-Y23L-4LEA>

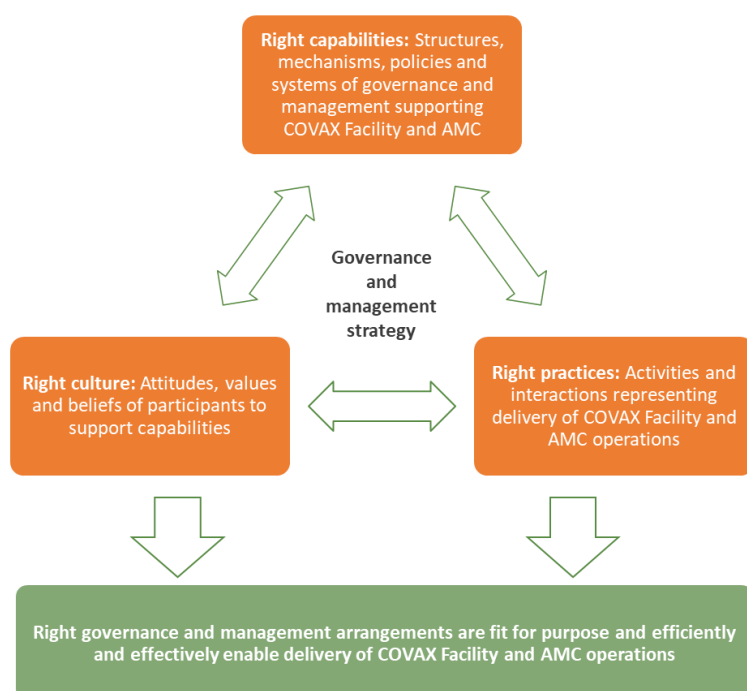
⁹¹ Daniels, N. and Sabin, J. (2006). *Limits to Health Care: Fair Procedures, Democratic Deliberation, and the Legitimacy Problem for Insurers*. Philosophy & Public Affairs, 26 (4), 303–50. <https://doi.org/10.1111/j.1088-4963.1997.tb00082.x>

global level, this will cover the operational aspects of the ToC through the following frameworks, norms and standards:

Capability, culture and practice mapping

This will be used as a benchmark to assess the governance and management arrangements for EQ 2.1.1 in place to support the operations of the COVAX Facility and COVAX AMC, in understanding the way accountability works in the relationship between key stakeholders at different levels, and the reasons/drivers for any failures or successes. The method draws on the approach used in Global Accountability Reports⁹² and the Multilateral Organisation Performance Assessment Network (MOPAN) 3.1 methodology,⁹³ as articulated in Figure 13 (below).

Figure 13 - Components of governance and management arrangements for analysis



This provides a helpful framework to understand whether the right conditions are/were in place to best enable and support COVAX Facility and AMC operations. For instance, it may be that a good management structure and policy is in place and that there is a culture which would help promote adherence, but that there is some confusion in terms of responsibility or a lack of coordination between various internal actors, constraining success. Our initial impression is that there is some ambiguity and difference of opinion regarding roles and responsibilities in management arrangements, particularly between the Office of the COVAX Facility and wider Gavi Secretariat and other COVAX implementing partners, and also in some governance structures. Where issues are identified, a RACI (Responsible, Accountable, Consulted,

⁹² Based on the framing adopted in the Accountability Reports 2008 and 2011: Lloyd, R., Warren, S. and Hammer M. (2008). *2008 Global Accountability Report*. One World Trust. https://acfid.asn.au/sites/site.acfid/files/resource_document/Pathways-to-Accountability-II.pdf; Hammer M. and Lloyd R. (2011). *Pathways to Accountability II - The 2011 revised Global Accountability Framework*. One World Trust. http://www.oneworldtrust.org/uploads/1/0/8/9/108989709/2008_global_accountability_report.pdf

⁹³ https://www.mopanonline.org/ourwork/themopapproach/Methodology_3.1_FinalUnformatted.pdf

Informed) analysis, drawing on the stakeholder mapping, may be used to test where accountability and responsibility sit within the relevant governance and management structures.⁹⁴

For the formative review and baseline study, this will involve an assessment of:

- *Capabilities* – the extent to which procedures, mechanisms, processes and roles and responsibilities are clearly documented and distributed to stakeholders.
- *Culture* – whether the attitudes and behaviors of staff, such as their perceptions of external stakeholders and how they interact with them, support capabilities.
- *Practices* – whether there is any divergence between what is included in the formal documentation and what happens in practice.

For management specifically, we will draw on established literature to support the diagnosis of issues arising and solutions, such as Cross and Carboni's (2021) categorization of patterns of network connectivity and collaborative practices that lead to dysfunction which undermine performance.⁹⁵

For governance specifically, we will evaluate whether the key principles agreed upon by the COVAX implementing partners to guide good governance in the COVAX collaboration were followed as intended:⁹⁶

- Governance structures provide a comprehensive view on the investment of public funds, enabling the right decisions to be taken in a timely manner.
- Appropriate members are selected for critical advisory groups.
- Decision making is done in an impartial and fair manner, with appropriate consideration given to conflicts of interest, which are identified and managed appropriately.
- Information on critical discussions and progress is provided in a transparent and timely manner.

This assessment will likely be expanded in later stages of the evaluation.

Risk management analysis

The evaluative enquiry for EQ 2.1.2 will be focused on systematically documenting how risk management processes have been designed and delivered to comprehensively identify and prioritize financial and programmatic risks. This will include a detailed review of the risk assessment strategy documentation produced by the COVAX Facility and COVAX AMC.

The design will be assessed against the ISO 3100:2018(en): 'Risk Management – Guidelines' as a benchmark comparison framework.⁹⁷ This exerts that managing risk is based on the principles, framework and process set out in Figure 14, where the:

- principles are the foundation for managing risk and should enable an organization to manage the effects of uncertainty on its objectives;

⁹⁴ RACI analysis would describe the participation of the various stakeholders in completing activities or deliverables for an organization's processes, and will plot this in terms of who is responsible, who is accountable, who is consulted and who is informed for each process. This is presented in a matrix and used to map where accountability and responsibility sit within an organization/management structure, as well as where gaps in roles and responsibilities may exist and/or where there are any apparent or real conflicts of interest. It would also be helpful to analyse how any tensions within the existing arrangements may shift as responsibilities and accountabilities move.

⁹⁵ Cross, R. and Carboni, I. (2021). *When collaboration fails and how to fix it*. MIT Sloan Management Review. Winter 2021.

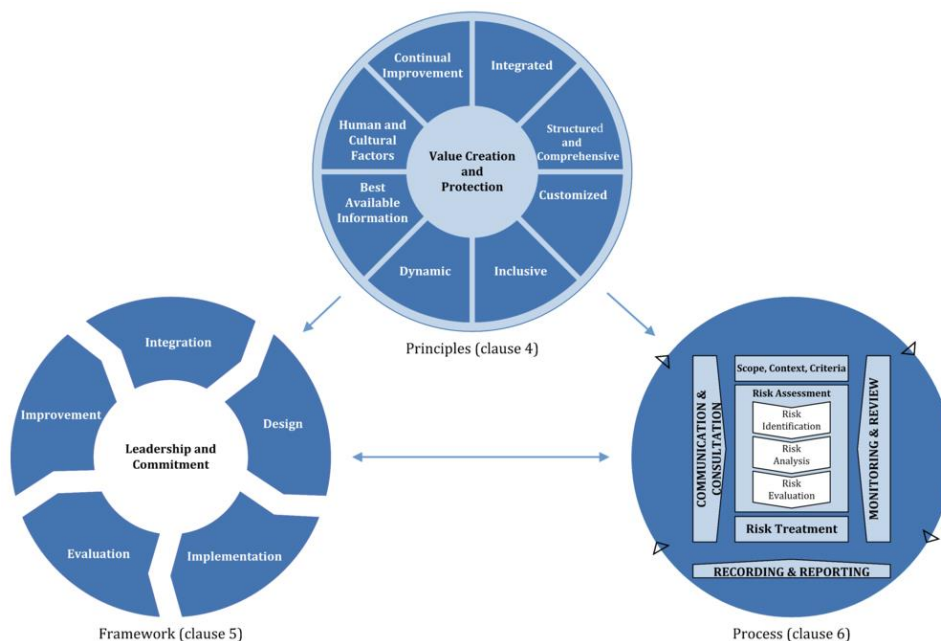
⁹⁶ COVAX. (2020, 17 March). *COVAX: The Vaccine Pillar of the access to COVID-19 tools (ACT) accelerator structure and principles*.

⁹⁷ International Organization for Standardization. (2018). *Risk management — Guidelines*. (ISO Standard No. 31000:2018).

<https://www.iso.org/obp/ui/#iso:std:iso:31000:ed-2:v1:en>

- framework assists the organization to integrate risk management into significant activities and functions, i.e. through its governance and management; and
- process ensures the systematic application of policies, procedures and practices to the activities of communicating and consulting, establishing the context and assessing, treating, monitoring, reviewing, recording and reporting risk.

Figure 14 – Components of the ISO risk management guidelines⁹⁸



This benchmark will be used to assess the design of the risk management function, considering the particular needs of operating within and seeking to address a public health emergency, and will also identify where issues have arisen and how these link to deficiencies in the design over time. This will be linked to the timeline analysis. For instance, key events include the appointment of Gavi as being the host and administrator for the COVAX Facility (30 July 2020); the establishment of the Gavi governance committee (8 October 2021); the news that the Serum Institute India announced delays in production (25 March 2021); and the COVAX global supply forecast release (8 September 2021).

The analysis will also benefit from comparison to Gavi’s business and usual approach to risk management.

Costing assessment

For EQ 2.1.3 we will review the available documentation in order to understand the resource envelope approved by the Board to administer the Office of the COVAX Facility and the actual costs of implementing the COVAX Facility and COVAX AMC, both in total and as a percentage of the total budget/expenditure, which will be benchmarked to various other agencies working in global health and emergency response.

If data is made available, we would also conduct a detailed costing analysis of some of the core processes implemented by the Office of the COVAX Facility. This would involve estimating the cost of specific core processes that are central to the COVAX Facility and COVAX AMC ToC and mapping these out in detail (what has been done, by when and by whom, and allocating costs to different steps based on how long people spend delivering them and how many people are involved). This will create a visual representation

⁹⁸ International Organization for Standardization. (2018). *Risk management — Guidelines*. (ISO Standard No. 31000:2018). <https://www.iso.org/obp/ui/#iso:std:iso:31000:ed-2:v1:en>

of the process and provide a template for analysis of how these core processes work in practice, what works well, and where the biggest inefficiencies have been.

Analysis of stakeholder engagement and communication

Building on the stakeholder mapping and analysis under Module 1 to determine stakeholder engagement and influence in design processes, additional analysis will be conducted for EQ 2.1.4 to map the relationships, influence and interactions between stakeholders during implementation, and to assess the communications processes and functions. To assess whether the level of stakeholder engagement in implementation is appropriate, we propose to draw upon existing benchmark assessment analytical tools (such as the AA1000 Stakeholder Engagement Standard,⁹⁹ the MEASURE stakeholder engagement tool¹⁰⁰ and the Stakeholder Engagement Model)¹⁰¹ as well as relationship index tools (such as the Edelman Relationship Index)¹⁰² to develop a bespoke benchmark assessment tool which can be used to assess the level of stakeholder engagement as well as the quality of this engagement. The analysis will also benefit from comparison to Gavi's 'business as usual' approach to stakeholder engagement and the approaches adopted by other agencies working in global health and emergency response.

Box 3: Note on comparator analysis

As noted elsewhere in this section, comparator analysis will be used across both operational and programmatic areas of the ToC and will provide highly useful information if: (a) the comparator is highly relevant to the element of the COVAX Facility and COVAX AMC being assessed; and (b) a detailed understanding can be gained on the specific, highly dynamic context that the operational structures and processes have operated in over time. Such analysis will be resource-intensive. For these reasons we will conduct only a few of the most relevant comparator analyses, focused on specific strategies or elements of the ToC. The proposal is for comparator analysis to be used in the following ways:

- To compare the cost of administering the Gavi Secretariat for implementation of the Gavi 5.0 Strategy to the cost of setting up the COVAX Facility and COVAX AMC. This comparison may be expanded to capture the set-up costs of other global health and emergency response initiatives with a similar mandate and proposed scale of operations.
- To compare stakeholder engagement, risk management, market shaping and procurement and delivery approaches used for the COVAX Facility and COVAX AMC to the Gavi approach to implementing the Gavi 5.0 Strategy.
- To compare the market shaping approaches used for the COVAX Facility and COVAX AMC to the approach used for the introduction of antiretroviral therapy (ART).
- To compare the procurement and delivery approaches used for the COVAX Facility and COVAX AMC to the approach used by the PAHO Revolving Fund.
- To compare the operationalization of the allocation mechanism for the COVAX Facility and COVAX AMC to the approaches used for the allocation of PPE or COVID-19 treatments through ACT-A, and also for H1N1 vaccines.

⁹⁹ AccountAbility. *AA1000 Series of Standards*. <https://www.accountability.org/standards/>

¹⁰⁰ MEASURE Evaluation. *Stakeholder Engagement - An assessment and implementation tool for identifying stakeholders in a data collection initiative and engaging them as contributors and beneficiaries*. https://www.globalhealthlearning.org/sites/default/files/page-files/DDIU_Stakeholder_Engagement.pdf

¹⁰¹ Morphy, T. *Stakeholder Engagement - Definition and Overview*. Stakeholder Map. <https://www.stakeholdermap.com/stakeholder-engagement.html>

¹⁰² Edelman. (2020). *2020 Edelman Trust Barometer*. <https://www.edelman.com/trust/2020-trust-barometer>

At the start of the baseline and formative review, we will articulate the rationale and specific criteria used for selecting comparators. C4D Principles on generalization¹⁰³ will be used to guide how we gather, frame and present the learning from comparators.

Process tracing

Process tracing will be used for ‘inward-out’ analysis (complementing the ‘outward-in’ analysis proposed under Module 3 – right results), to follow the use of inputs and activities up to the achievement of outputs. It will look across the ToC, taking a ‘*monitoring data plus*’ approach – i.e. it will use existing monitoring data alongside additional verification. ‘Testing’ will involve gathering evidence on how well the programmatic components have been implemented against the ToC to contribute to change. For example, to inform question 2.2.4, Gavi and UNICEF procurement information and administration systems will be analyzed to see what data was collected, how timely and complete the information was and the extent to which Gavi analyzed this data against country information to monitor equitable allocation and administration to identify and address problems in a timely manner.

During the baseline and formative evaluation stage, the focus will be on tracing key activities related to specific programmatic areas, as well as linkages across programmatic areas (e.g. coordination between CRD assessments and allocation decisions). An overall analysis will then be conducted to understand, across the ToC, which components are working as intended and which are not. Root cause analysis will be used in a complementary way to explore how and why the theory is or is not working as intended.

Root cause analysis

We will use root cause analysis to further explore, analyze and understand the root causes underlying observed challenges or successes identified through a variety of triangulated data sources. Root cause analysis moves beyond identifying what challenges or successes have occurred towards helping to determine why a particular challenge or success has occurred.

Rather than using root cause analysis in isolation, it will be combined with other analytic methods (e.g. force field analysis) as part of the broader evaluation – functioning as a tool to help the evaluation better describe and interrogate cause and effect within processes. Following our experiences across a number of complex evaluations, we anticipate that issues/challenges amenable to root cause analysis will be observable from a number of data sources (document review, KIIs, etc.). This is likely to generate a long list of implementation issues that are viewed as important by stakeholders. The root cause analysis is then used to create prioritized lists of causes, based on their perceived importance to key stakeholders.

C. Right results

Verifying and use of COVAX Monitoring and Reporting Framework indicators

This method involves the triangulation and analysis of the COVAX Monitoring and Reporting Framework with other data (i.e. from documents, information systems and anecdotal reporting) as part of a process of verification. This will provide a rounded assessment on the extent to which intended results have been achieved. This will include an assessment of whether equity goals have been or are likely to be achieved. It will need to consider: the distribution of and access to vaccines across country income categories; the distribution of and access to vaccines between countries; and the distribution of and access to vaccines within countries, such as between geographical areas and population groups.

Gavi has already established a Monitoring and Reporting framework for COVAX, with a number of indicators – particularly those relating to higher-level impacts – still under development. Our evaluation

¹⁰³ <https://www.betterevaluation.org/en/C4D-Hub/Synthesise/Generalise-findings>

approach to right results proposes to harness relevant data from this framework, for example against output metrics 11 (percentage of COVAX participants administering COVAX-supported doses as part of their COVID-19 response), 12 (number of COVID-19 Vaccine Delivery Support requests approved) and 13 (total resources (USD) disbursed to AMC participants through the COVID-19 Vaccine Delivery Support program); and outcome metrics 15.0 and 15.1 (COVID-19 vaccination coverage supported by COVAX – aggregate percentage across total population of COVAX participant countries). As outlined in the EA findings for right results (see Annex 6), a number of the metrics require further thinking and the methodology behind them is still under development, e.g. impact metrics 18 (number of COVID-19 deaths averted) and 19 (proxy metrics related to social and economic impacts).

This assessment of results will provide a snapshot in time that will be used for comparison in later evaluation processes. It will also highlight areas of high and low performance within the portfolio, the reasons for which will be explored through EQ 4.5 on what can be learned from different country experiences and applied to the COVAX Facility and/or COVAX AMC for the achievement of results.

Outward-in process tracing

In practice, for the evaluation this will mean testing the individual causal pathways outlined in the ToC to understand how the evaluand (the mechanism) is working in the prevailing context to facilitate the desired outcomes and impact.

This approach will build on the work conducted under Module 2 (right way) by following the stated results at outcome and impact levels back towards outputs, activities and inputs, in order to understand how and why change happens. This can be referred to as an 'outward-in' approach.

This method will be used iteratively, tracking backwards from the results repeatedly to refine and test the ToC causal pathways. This approach will provide an in-depth and nuanced understanding of how well the COVAX Facility and COVAX AMC has worked to achieve results in the prevailing context over time. This approach is therefore suitable to the shifting realities and context of the COVAX Facility and COVAX AMC, as it is dynamic and sensitive to changes in direction which may influence observed results and unintended consequences. The analysis will also enable identification of unintended consequences and barriers and enablers to the achievement of results.

Having tested the causal pathways across the programmatic components of the ToC, an overall analysis can be conducted on how these programmatic components have linked together and where and how the COVAX Facility and COVAX AMC has played a role in influencing the achievement of observed outcomes and overall goals related to equity. This can then be synthesized to support analysis of the COVAX Facility and COVAX AMC's contribution to results.

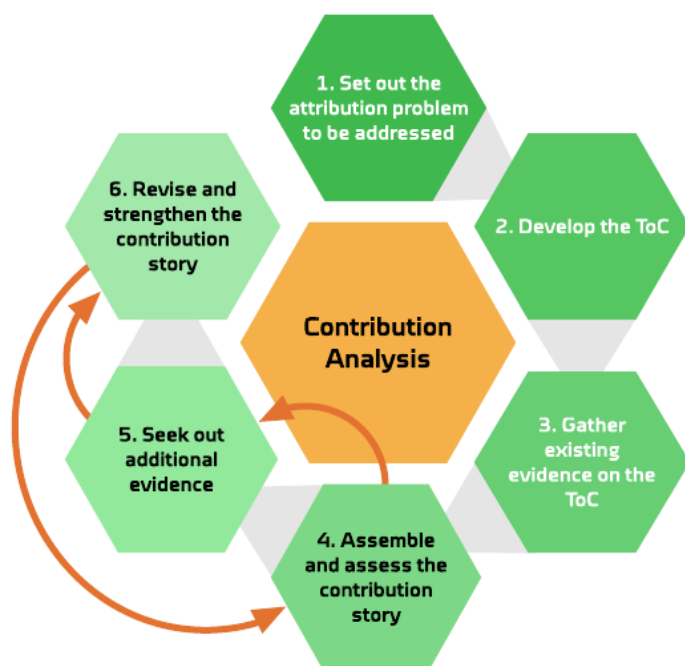
Contribution analysis

Contribution analysis is a method that was developed by John Mayne¹⁰⁴ and which is used to demonstrate a 'plausible association' and understand the likelihood that an intervention has contributed to an outcome observed, through a step-by-step process which explores how the contribution would have come about and which uses a broad range of evidence to test this.

The six steps involved are set out in Figure 15 (below).

¹⁰⁴ Mayne, J. 'Contribution Analysis: Addressing Cause and Effect' in K. Forss, M. Marra and R. Schwartz (eds.). (2011). *Evaluating the Complex*. Transaction Publishers. The full form of this methodology demands a number of repeat data collection rounds to build, test and strengthen the contribution story in an iterative way.

Figure 15 – Contribution analysis



Step 1: Delineate the causal issue and hypothesis to be tested. Contribution analysis is appropriate for answering the EQs – notably EQs 3 and 3.4, which are concerned with the contribution of the COVAX Facility and COVAX AMC to observed results.

Step 2: Develop a ToC. There are multiple types of ToC, and the type used in a given situation depends on what the theory is to be used for. Review of the contribution analysis literature, and discussion with people in the wider community of practice, points to using a ToC based on the ‘drivers’ that underpin a program and affect how it performs and what is delivered. There will be a series of underpinning drivers of the COVAX Facility and COVAX AMC that explain how and why the program is implemented as it is, how it

performs and what results it delivers at global and country levels. These drivers need to be identified and then, if assessing the contribution of the COVAX Facility and COVAX AMC is the main interest, it will be necessary to determine how what the COVAX Facility and COVAX AMC have done interacts with these drivers; and this affects how they in turn influence what is implemented and how. For example, a number of country-specific contribution analyses of Global Fund support to the achievement of programmatic results identified drivers related to political and social commitment to service delivery, the presence of barriers to accessing services, and health systems issues, as well as the actions of development partners and the Global Fund in particular. As noted elsewhere in the report, a ToC is under development and will be completed at the outset of the formative review and baseline study.

Step 3: Gather the existing evidence on the ToC. A range of evidence, particularly in relation to documents and from information systems, has already been collected through the EA, although it will need to be updated to account for recent developments and to capture all parts of the ToC. Much will come from the process tracing work and root cause analysis, but we also expect to collect a significant amount of the evidence required through KIIs, focus group discussions and country case studies.

Step 4: Assemble and assess the contribution story and challenges to it. With the information and evidence assembled, a contribution story will be drafted that sets out why it is reasonable to assume that the actions of the COVAX Facility and COVAX AMC and operation of the drivers have contributed to the observed outcomes. We then have to assess how credible this story is: will reasonable people agree with the story? Does the pattern of results observed validate the results chain? Where are the main weaknesses in the story? There always will be weaknesses: these point to where additional data or information is needed.

Step 5: Seek out additional evidence. Having identified where the contribution story is less credible, we will then gather additional evidence in terms of the results that have occurred, the reasonableness of key assumptions, and the role of external influences and other contributing factors.

Step 6: Revise and, where the additional evidence permits, strengthen the contribution story. With the new evidence, we should be able to build a more substantive and therefore more credible story – one that a reasonable person will be more likely to agree with. It will probably not be definitive, but the additional

evidence will have made it stronger and more plausible. Using a generative perspective, contribution analysis argues that a reasonable claim of causal contribution can be made if:

- There is a reasoned ToC: the key assumptions behind why change was expected to work make sense, are plausible, can be supported by evidence and/or existing research, and are agreed upon by at least some of the key players.
- The activities were implemented as set out in the ToC. This can be partly answered through the process mapping/nested ToC work.
- The ToC – or key elements thereof – is supported and confirmed by evidence on observed results and underlying assumptions. The chain of expected results occurred. The ToC has not been disproved.
- Other influencing factors have been assessed and *either* have been shown not to have made a significant contribution *or* their relative role in contributing to the desired result has been recognized.

It is anticipated that an increasing focus will be given to the ‘right results’ module, and to this method in particular, throughout the stages of the evaluation. Given the relatively early timeline of implementation and the clear appetite among stakeholders to understand the implications of design choices and implementation processes, the formative review and baseline study will involve a lighter-touch focus on outcomes and impacts and will not involve detailed contribution analysis.

D. Cross-cutting methods

A number of methods will be applied across the scope of work, as follows:

History of decisions and timeline analysis

As per Section 2.2, across all the EQs, in order to generate a clear understanding of the specific contexts in which operational structures and processes were implemented, there will need to be a forensic construction of a timeline for the COVAX Facility and COVAX AMC operations for each of the stages under review. We have developed a preliminary version of a timeline as part of the EA in Annex 13. This will be further developed to provide a comprehensive overview of implementation decisions to date and the specific context in which these decisions were made and in which operational structures and processes were implemented. This will draw on secondary data and substantial qualitative data collection from the stakeholders engaged in implementation.

Cross-case study analysis

Case studies will be used across the EQs for the programmatic components of the ToC. Cross-case analysis will be used to draw lessons from across different country contexts, for example to identify enabling conditions and barriers to providing effective TA for CRD, depending on country-specific contextual factors. Cross-case analysis will also be useful to look across a broad spectrum of AMC countries (LICs and LMICs) and SFP countries (upper-middle-income countries (UMICs) and HICs) to understand, for instance, the extent to which vaccine allocation aligned with country needs and preferences, and the extent to which country readiness assessments were integrated into planning for allocation and procurement across different country cases.

Synthesis

As noted in Section 3.4.3, we expect synthesis to take place regularly and at multiple levels, including:

- *Country case study level:* Analysis of data and synthesis of findings at individual country case study level and across country case studies

- *For specific EQs:* This will provide responses to EQs related to identifying unintended consequences and barriers and enablers to desired changes
- *By module:* Analysis of data against individual EQs synthesized through the lenses of right things, right way, right results and learning
- *By programmatic area:* Analysis of data synthesized through the lenses of resource mobilization, market shaping, procurement and delivery, equitable allocation and CRD
- *Cross-module:* Analysis of data synthesized to identify overall strengths and weaknesses
- *For equity:* Synthesis to understand how equity has been considered in both the design of the COVAX Facility and COVAX AMC (equity in process) and results achieved (equity in outcomes). (See Table 5)

The synthesis process should involve a series of steps to ensure a systematic, rigorous qualitative analysis:

Step 1: Familiarization: Team members review data collected, collate and analyse for each EQ, and familiarize themselves with the data, likely contained in evidence matrices and in drafted report sections. Notes are to be made on potential themes identified in this first round to inform coding, and clarifications raised with the other team members, as needed.

Step 2: Generating an initial structural coding framework: After the initial reading, a coding framework should be generated, based on the agreed ToC, EQs and broad areas of interest (see suggested synthesis levels above). Specialist coding software may facilitate data management for this process.

Step 3: Iterative coding: Team members code data for one or more EQs and identify emerging themes. Each EQ is coded by more than one team member, and, where there were differences in the coding, we reviewed this, discussed and reconciled (through further analysis if needed). This iterative process of coding and review serves to test the themes and discuss differences and interpretation against our original framework. To reconcile differences, problem tree analysis is conducted into cause and effect links. From this process, some new broader themes are likely to be identified, and codes consolidated into these. The broader themes are then tested and refined through a second round of coding and, where relevant, sub-themes are derived to reflect different dimensions within each theme. Broader themes are then tested and refined as needed.

Step 4: Interpretation workshop: Team members discuss the coded data and refine the themes and sub-themes to arrive at agreed interpretations. The workshop process should follow a systematic approach to explore, challenge and consolidate the themes and findings – for instance:¹⁰⁵

1. **Determining how evidence is related:** identifying points of comparison or opposition within the reports and case studies, and identifying ‘lines of argument’ – inferences that cut across cases – through ‘comparing and sorting interpretations, examining similarities and differences, and then integrating or framing these within a new interpretation’ that applies across cases.¹⁰⁶
2. **Translation:** periodically revisiting the module reports and underlying data to attempt to ‘translate’ evolving concepts or themes back into the source data, checking to see how far they accurately reflected case study findings, and scrutinizing conceptual differences.
3. **Juxtaposing** insights from one report to make sense of a pattern noted in another.
4. **Reconciling** contradictory insights through unearthing differences that might lead to different outcomes.

¹⁰⁵ Noblit, G. W. and Hare, R. D. (1988). *Meta-ethnography: Synthesizing qualitative studies*. Newbury Park, Calif: Sage Publications.

¹⁰⁶ Pope, C., Mays, N. and Popay, J. (2007). *Synthesizing Qualitative and Quantitative Health Evidence: A Guide to Methods*. Maidenhead: Open University Press.

5. **Adjudicating** between contradictory findings from the reports to identify strengths and weaknesses in the original conclusions, and the strength of the underpinning evidence.

Step 5: Drafting: Team members each draft synthesized findings/conclusions/recommendations for one or more thematic areas, developing the interpretation further. The subsections are then reviewed and agreed by the wider team and integrated into the report.

It will also be important to work alongside the Office of the COVAX Facility to co-create conclusions and recommendations. These processes work best where stakeholders have seen draft findings in advance and have had an opportunity to provide initial comments. Allowing this before the workshop will help to ensure that stakeholders provide a more reflective perspective, which, based on our experience, generates a more conducive environment for thinking through overall conclusions and recommendations on how best to move forward. For the avoidance of doubt, while the co-creation process should help to build consensus on conclusions and recommendations, these should remain the responsibility of the independent evaluators, who must be free to reject suggestions of others if it is felt appropriate to do so.

Validation and prioritization of lessons learned

To validate and prioritize high quality lessons, we propose a lesson-learning *framework of criteria*¹⁰⁷ to provide a clear definition of what constitutes valid 'lessons learned'. In practice this means assessing the strength, importance and relevance of lessons emerging from formative-summative and rapid evaluation activity. See below (Table 22).

Table 22 - Lessons learned framework of criteria

Criteria for good lessons learned development	How they can be applied in practice
1. They are owned (by people who are ready to talk about them)	Ensuring COVAX team and other relevant stakeholder groups are engaged in exploring and adding depth/validation to lessons learned that emerge from evaluation activity.
2. They are based on experience (which may be positive or negative)	Built into evaluation design – ensuring all relevant stakeholder groups have the opportunities to participate in ways accessible to them.
3. They are verifiable (because the events involved are documented)	Synthesizing findings across evaluation components 1, 2 and 3 which arise from rigorous evaluation effort.
4. They are useful to others (who read or hear about them)	To be explored during sense-making workshops with key stakeholder groups – noting that the composition of groups may change over time. Groups will need to be defined and adjusted based on timing of evaluation activity and 'area' of lesson.
5. They make a difference (when acted upon) <i>in contrast with generalizations, which – while likely to be true – offer no implications for specific actions</i>	
6. They are contextually grounded	
7. They have wide applicability (wider than recommendations) but they do not have universal applicability (i.e. not physical laws or moral truths)	To be validated through group critical reflection with key stakeholder groups, e.g. Gavi 5.0 colleagues, external agencies working in pandemic preparedness and response (comparators).

Lessons learned will rely on a process that includes:

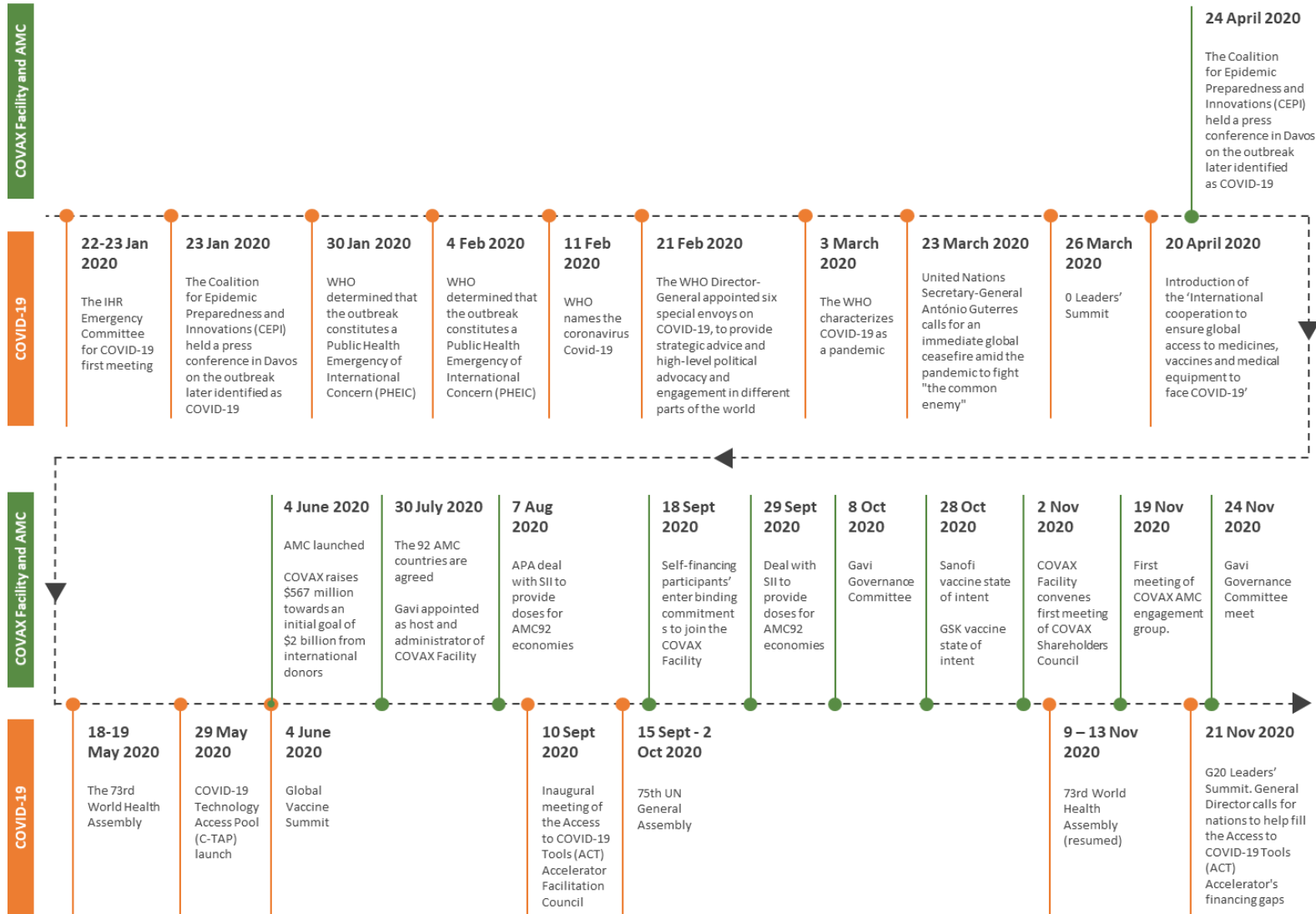
- Robust triangulation of data sources – e.g. through KIIs, focus group discussions and document review used through Modules 1 to 3.

¹⁰⁷ Davies, R. (2009, August 26). *Expectations about identifying and documenting "Lessons Learned"*. <https://mande.co.uk/wp-content/uploads/2009/08/2009%2008%2026%20Guidance%20on%20identifying%20and%20documenting%20LL%20vs2.pdf>

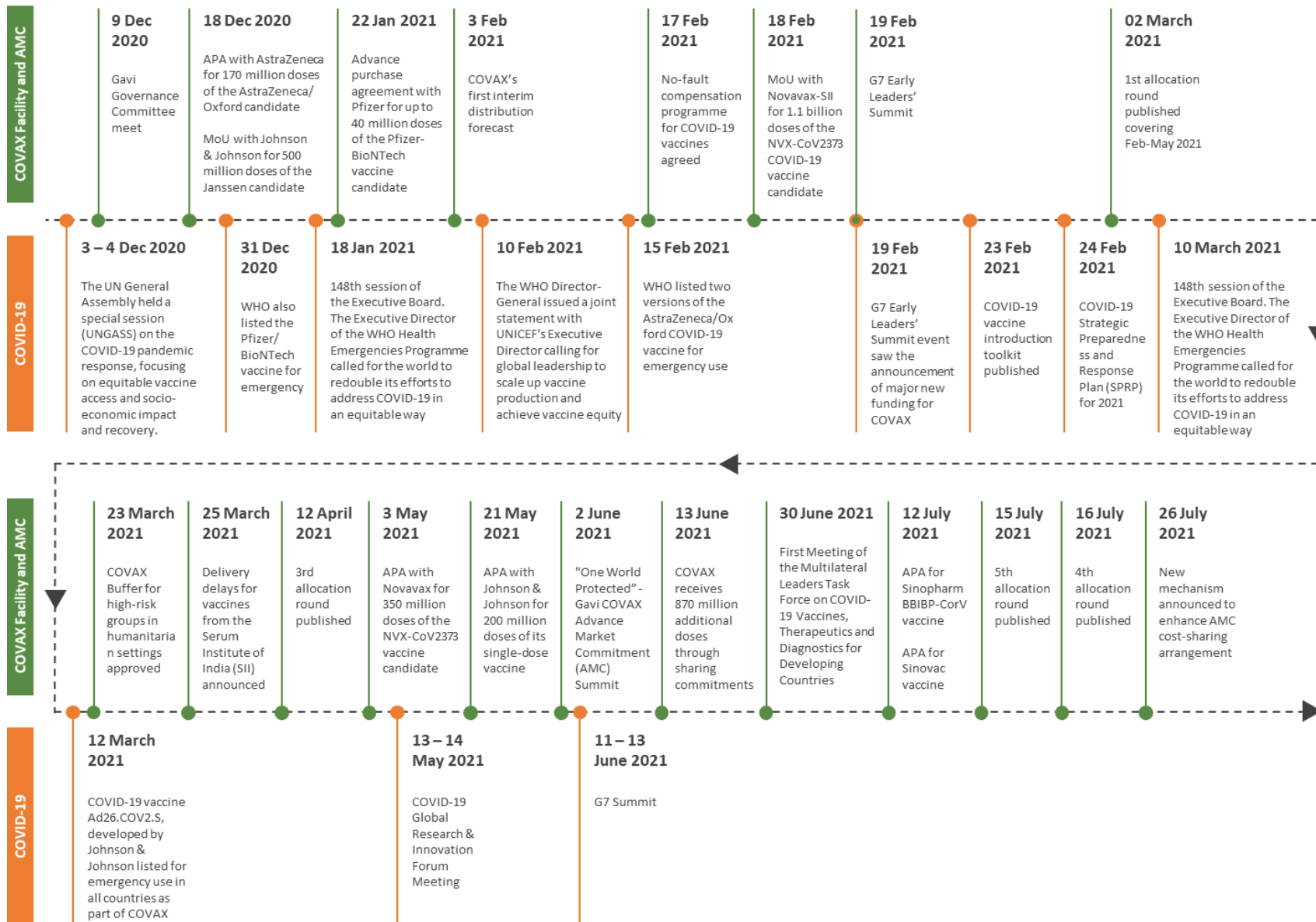
- Good quality synthesis – as outlined in Section 3.4.3. The approach to synthesis requires combining multiple sources of information to develop a fuller understanding of what is happening in an area of enquiry. Synthesis can strengthen patterns and ideas or theories emerging from findings. We will adopt this approach to synthesize information in a written form gathered through evaluation components 1 to 3. Within these syntheses we recommend profiling the most important lessons learned through synthesis products, as outlined in the dissemination plan.
- A participatory process with relevant stakeholder groups to explore and sense-check lessons learned that have emerged using the criteria enclosed in Table 23. This should be facilitated by someone proficient in group critical evaluation and sense-making workshops in complicated intervention designs.

Annex 13: Timeline

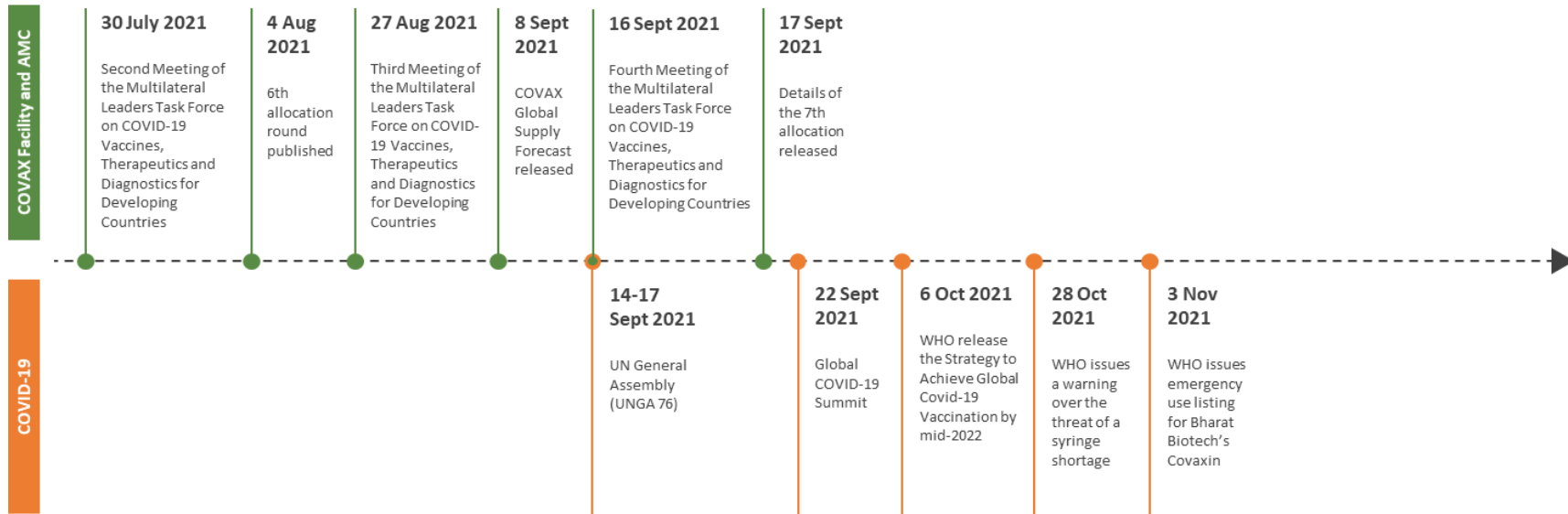
Figure 16 – COVAX timeline



Final evaluability assessment and evaluation design report



Final evaluability assessment and evaluation design report



Annex 14: Integration and added value of rapid reviews

Figure 17 (below) illustrates how rapid reviews complement and add value to the overall formative-summative evaluations and continuous learning function led by the Office of the COVAX Facility/Gavi ELU.

Figure 17 - The value of rapid reviews to compliment formative-summative evaluations and continuous learning function

How do rapid reviews complement and add value to formative-summative evaluations and continuous learning for the COVAX MEL function?

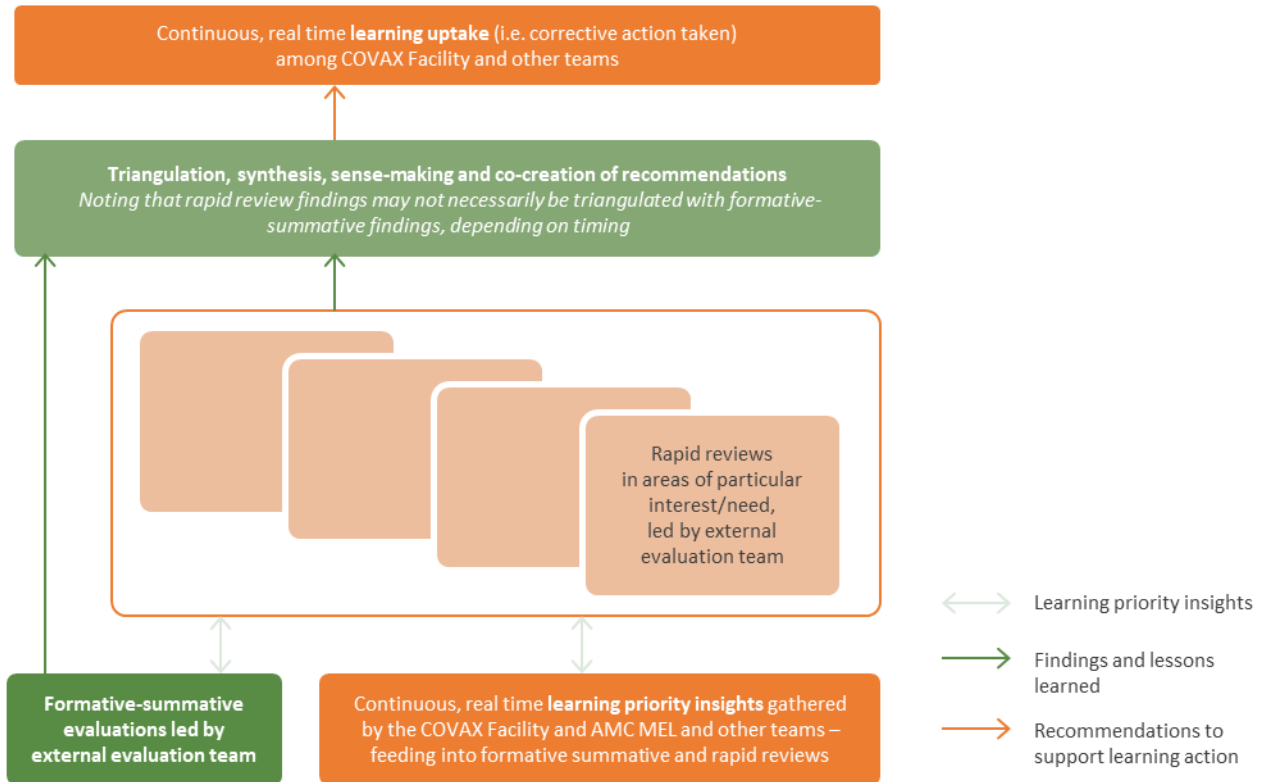
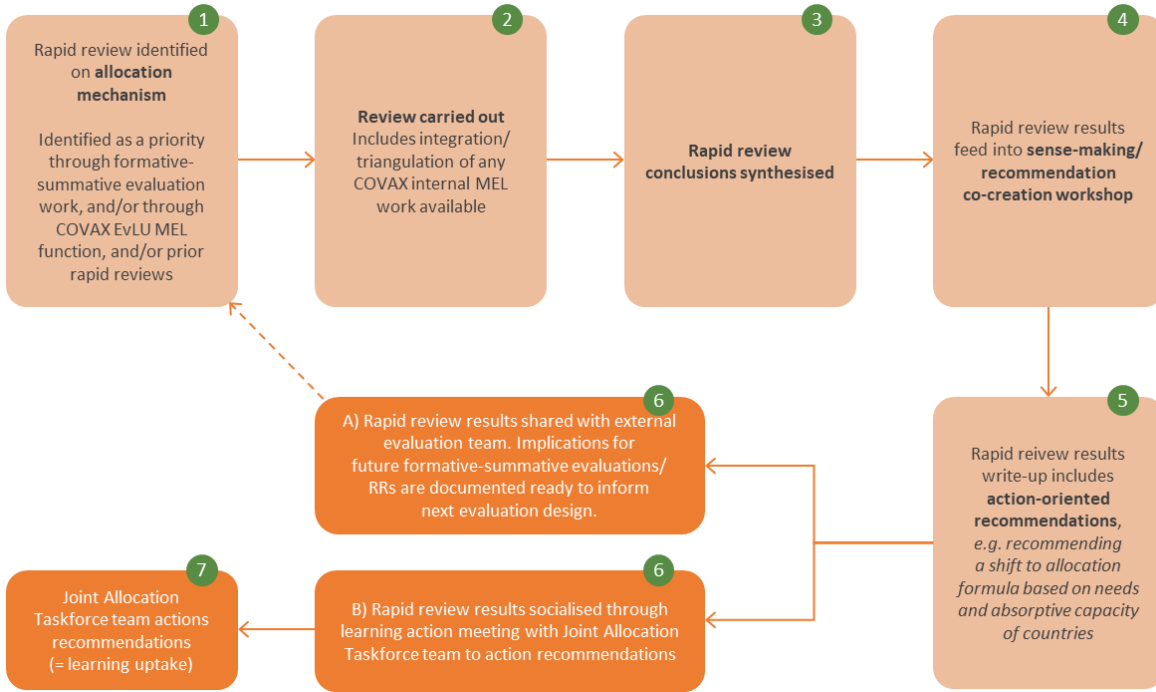


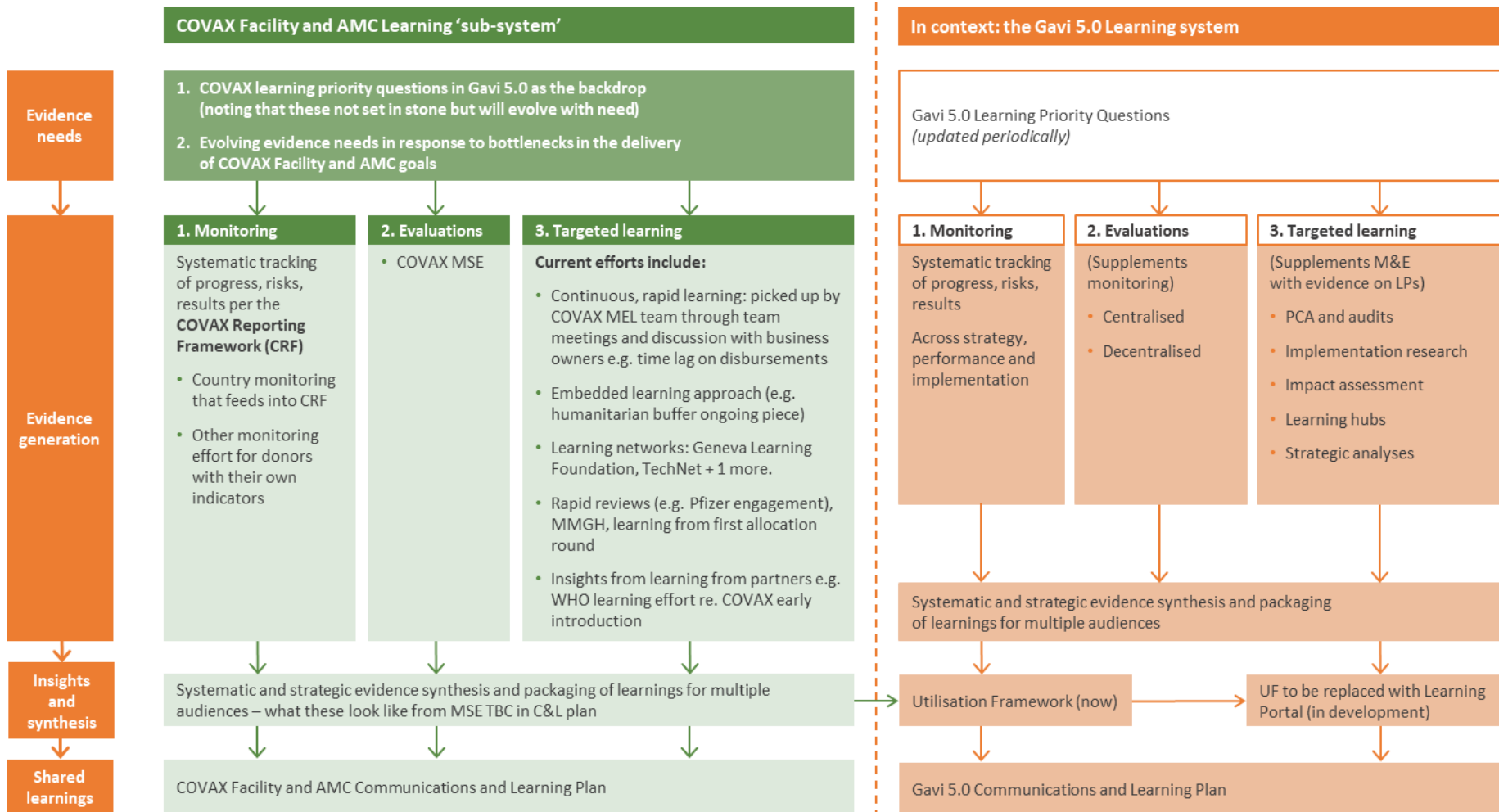
Figure 18 provides an example process of how rapid reviews are envisaged to inform course correction.

Figure 18 - How rapid reviews can inform course correction



Annex 15: Visual map of COVAX Facility and AMC learning system

Figure 19 - Visual map of COVAX Facility and AMC learning system



Annex 16: Communication and learning plan

Overall, we recommend a communications approach that takes *utilisation, reporting and supporting use* dimensions into account. To inform this approach we have drawn on working sessions with the ELU, KIIs and the online survey.

Utilisation focus: We recognise the significant demand for learning and sharing of key achievements, lessons learned and proposed revisions to COVAX Facility and AMC design. We also recognise the inherent risk with evaluation work; that it does not achieve its intent. This can be due to a combination of factors, including insufficient engagement with the right stakeholder groups, and not ensuring a balanced representation of voices within all phases of the evaluation (especially among the ‘voiceless’ or hard to reach groups).¹⁰⁸ We recognise that evaluation impact can be limited when a specific and user-focused communication approach is not adopted from the start.

The strong utilization focus woven through this evaluability assessment and evaluability design work process has attempted to mitigate this risk. This focus will need to continue throughout future multi-stage evaluation efforts.

With this in mind we have developed a draft C&L plan for COVAX Facility and AMC through a systematic process. This process builds on the detailed stakeholder mapping efforts that took place during the inception phase. It includes five key steps:

Step 1: Using findings from the stakeholder mapping exercise during Inception Phase we identified five broad stakeholder groups. These were determined based around their core functions:

1. **Accountable for performance** of COVAX Facility and AMC. Key to decision making: PPC and Gavi Board.
2. **Responsible for delivery** of COVAX Facility and COVAX AMC: Office of the COVAX Facility.
3. **Joint responsibility in delivering the COVAX Facility and COVAX AMC:** CEPI, WHO, UNICEF, PAHO.
4. **Constituent groups representing specific interests within the Gavi Board:** CSOs, governments (AMC Engagement Group, Shareholders Council), vaccine industry, research and technical health institutes.
5. **Perception shaping role:** the media.

Step 2: Identified 10 constituent subgroups across these five broad groups.

Step 3: Identified learning ‘use cases’ for each subgroup – i.e. considering their likely learning and communication needs.

Step 4: Developed a communication and learning pathway for each group as shown in the C&L plan (Table 24).

Step 5: Developed a draft dissemination plan to highlight products to be shared using time as the primary unit of analysis e.g. what will be shared at baseline, multi-stage evaluation points etc.

We recognise the limitations of this plan, not least as we have not yet spoken to many country-level stakeholders including CSOs and ministries of health/immunisation programme teams to gauge their needs. We expect to hone the C&L and dissemination plans ahead of the final evaluability assessment/evaluability design report as we speak to more key informants. We also welcome further interrogation of this plan with the COVAX MEL and communications teams.

Reporting and supporting use: Attention to both reporting and supporting use are integral to a strong communication and learning approach.

¹⁰⁸ https://evaluationstories.files.wordpress.com/2015/11/evaluations-that-make-a-difference-en_21sep15.pdf

Different types of reporting and synthesis products will be useful for different groups, to suit the type and complexity of information to be conveyed, and the result anticipated through communication. As outlined below and in the dissemination plan (Annex 17), reporting and synthesis products could include executive summaries / interim reports/ synthesis products / briefs/ slide decks / infographics/ brief videos and use of social media platforms to share evaluation key findings to enhance accessibility.

In terms of the topics or themes for synthesis and learning products we would anticipate these including – but not being limited to – the topics below:

- Barriers and enablers to achieving the outcomes and goals in the COVAX ToC and how these relate to course correction needs within the COVAX Facility and AMC
- Country-level learning including equity implications for COVAX Facility and AMC course correction, the wider Gavi 5.0 and future pandemic preparedness and response
- Specific learning emerging from specific areas of the ToC (e.g. learning on manufacturers engagement, use of humanitarian buffer, procurement, etc.)

We would anticipate additional synthesis and learning products being produced as key themes and lessons learned emerge. The framing and titles of products will require careful thought, honing and nuancing to meet target audience needs as these evolve over time.

To maximise the likelihood of evaluation findings and products being used to inform change as intended, Table 23 outlines the recommended set of activities be woven through the multi-stage evaluation.

Table 23 - Recommended formative learning and communication activities

Within the evaluation team	Within the Office of COVAX Facility and COVAX AMC leadership team & COVAX MEL and Communications team
Communications and learning plan – to frame C&L efforts	
The main tool to frame ‘use’ is to develop and communications and learning plan – outlining communication and learning needs of different evaluation stakeholder groups, types of products, channels of communication, intended results for each.	Find opportunities to integrate COVAX Facility and COVAX AMC learning in the wider Gavi 5.0 C&L plan.
Learning Point - to check Learning Priorities	
Make best use of ‘Learning Points’ – to check learning priorities and reinforce triple loop learning. Ensure skilled facilitation for these sessions.	Make best use of ‘Learning Points’ – to check learning priorities and reinforce triple loop learning. Ensure right stakeholders are committed to this process through active, recurrent participation.
Sharing of interim and emerging lessons - to generate interest and engagements in evaluation activity	
Include interim as well as final presentations to specific COVAX Facility and COVAX AMC and wider Gavi groups to socialise emerging findings / emerging recommendations.	Ensure right stakeholders attend right meetings to maximise chances of use.
Use of group critical reflection and sense-making sessions - to strengthen utility of recommendations	
Lead and facilitate ‘group critical reflection’ and ‘sense-making’ approaches to test lessons and ground them in context.	Ensure right stakeholders are committed to this process through active, recurrent participation. Through participation and observation invite colleagues who may be keen to develop skills to run these sessions internally.
Sharing summative findings through accessible synthesis products and social media - to engage broader audiences and be transparent with findings	
To increase external reach and use of multi-stage evaluation findings: Sharing summative findings through lessons learned synthesis products – especially with learning relevant for future pandemics through traditional written briefs/ reports + accessible methods e.g. infographics to repurpose and reinforce key content.	To increase external reach and use of multi-stage evaluation findings: Sharing summative findings through lessons learned synthesis products – especially with learning relevant for future pandemics through traditional written briefs/ reports + accessible methods e.g. social media , infographics to repurpose and reinforce key content.
Recommendations tracking - to check if and how learning is being used, is it useful	

	Recommendations tracking from baseline and evaluation findings “To follow future supposed applications of lessons learned to test their wisdom in action.” ¹⁰⁹
Observation and documentation of learning behaviours - to reinforce LS culture	
	Observe and document COVAX teams learning behaviours – i.e. how the COVAX teams are modelling desirable learning behaviours. This is desired through Gavi 5.0 LS. Would be drawing out what behaviours are happening in COVAX team that could be identified, documented and shared more widely with Gavi 5.0 LS context.
Ensure COVAX Facility and learning is located in the Gavi 5.0 Learning System - to reinforce LS content and use of centralised system	
	Ensure evaluation reports, learning and synthesis products are systematically uploaded to the Gavi 5.0 UF/ Learning Portal (as well as COVAX learning library) to maximize chances of its use.

Table 24 presents the overall communication and learning plan.

¹⁰⁹ <https://archive.globalfrp.org/evaluation/the-evaluation-exchange/issue-archive/learning-organizations/lessons-learned>

Table 24 - Communication and learning plan

About the user					About how to engage them through C&L efforts						Timing
Learning need	EQs of interest (priority order)	Intended user group	What learning result (action/state) do we expect?	Framing needs	Stakeholder matrix quadrant classification ¹¹⁰	Timing of communication	Type of learning product/activity	Channels for distribution	Responsibility for production	Responsibility for dissemination	
<p>Immediate need: To understand where major COVAX Facility and AMC course corrections are needed - both programmatic and operational</p> <p>Longer term: How can COVAX Facility and AMC learning be leveraged for achievement of Gavi 5.0 goals & future pandemic preparedness and response</p>	4 3 1 2	PPC and Gavi Board	PPC fully informed and clear on what to recommend to Board	Needs robust analysis with sensitivity given level of personal & professional investment and burn-out, as well as contextualisation	Actively engage	Regular - throughout MSE	Interim findings for meetings Evaluation reports Synthesis products	Reporting into Office of the COVAX Facility via ELU PPC and Board meetings – routine and extraordinary	Evaluation entities drawing on inputs from relevant stakeholder groups	ELU	<p>Phase 1, 2022-2023: Immediate course correction findings (and implications for Gavi 5.0) of formative review and baseline to be available ahead of Oct PPC and Nov Board meetings in 2022</p> <p>Phase 2: 2024-2027 Longer-term future pandemic preparedness findings to be available from 2024</p>
		Office of the COVAX Facility	PPC and Board confident in using evaluation recommendations. Office of the COVAX Facility understand and agree to implement								
To understand what advice/recommendations the Office of the COVAX Facility need to make operational and programmatic decisions	4 3 1 2	Office of the COVAX Facility Key bodies engaged in the governance and oversight of COVAX Facility and AMC operations ¹¹¹	Most important lessons and recommendations for course correction are actioned	Needs robust analysis with sensitivity given level of personal & professional investment and burn-out, as well as contextualisation	Actively engage	Regular - throughout MSE	Interim findings for meetings Engagement in co-creation, learning points, sense-making workshops as relevant Evaluation reports Synthesis products	Respective team/committee meetings.	Evaluation entities drawing on inputs from relevant stakeholder groups	ELU	<p>Phase 1, 2022-2023: Immediate course correction findings (and implications for Gavi 5.0) of formative review and baseline to be available ahead of Oct PPC and Nov Board meetings in 2022</p>
To understand what actions other COVAX implementing partners	4 2	Gavi, WHO, UNICEF, CEPI, PAHO	Most important lessons and recommendations	Needs a partnership working lens	Actively engage	Regular - throughout MSE	Engagement in evaluation	Respective team/	Evaluation entities drawing on	ELU	a) For course correction needs (and implications)

¹¹⁰ This is a matrix to help classify stakeholders into groups based on certain criteria. In this instance we created categories to determine the level of engagement we anticipate each group needing, to fulfill their learning and communication needs. Categories include Actively engage, ensure aligned, keep informed. Source: Stakeholder matrix - key matrices for stakeholder analysis <https://www.stakeholdermap.com/stakeholder-matrix.html>

¹¹¹ See COVAX. (2020, 17 March). *COVAX: The Vaccine Pillar of the access to COVID-19 tools (ACT) accelerator structure and principles*.

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may need to take a) to course correct in the way they interact/ collaborate with Gavi, and b) to inform future pandemic preparedness and response efforts	3 1		ns for course correction are actioned	and understanding of working relationships between partners and different areas of expertise			activity, recommendations on co-creation, learning points, sense-making workshops as relevant Evaluation reports Synthesis products	committee meetings.	inputs from relevant stakeholder groups		for Gavi 5.0): Phase 1 findings of formative review and baseline to be available ahead of Oct PPC and Nov Board meetings in 2022 b) For longer term future pandemic preparedness: Phase 2: 2024-2027 & Phase 3, 2028-2030
To understand CSO engagement in COVAX Facility and AMC and what role CSO's can play in course correction and future pandemic preparedness	4 3 2 1	Civil society	For CSOs to feel a) meaningfully engaged and represented in processes; and b) confident in advocating for change and using evaluation outputs to do so	Should be clear on how CSOs are engaged in COVAX Facility/AMC implementation, including clarity on how their engagement supports equity dimensions	Actively engage	Regular - throughout MSE	Engagement in evaluation activity, recommendations on co-creation, learning points, sense-making workshops as relevant Evaluation reports Synthesis products	Through Gavi Board, existing CSO networks at Gavi as well as through independent CSO alliances	Evaluation entities drawing on inputs from relevant stakeholder groups	ELU	Phase 1, 2022-2023: Immediate course correction findings (and implications for Gavi 5.0) of formative review and baseline to be available ahead of Oct PPC and Nov Board meetings in 2022 For longer term future pandemic preparedness: Phase 2: 2024-2027 & Phase 3, 2028-2030
To understand where course corrections are needed to ensure equitable access to COVID-19 vaccines through COVAX, balancing supply availability and country readiness to utilise vaccines Understand how countries can continue to engage with the COVAX Facility, and gain information desired (e.g. on supply) to improve country readiness	4 3 2 1	Governments – mostly focused on low- and lower-middle income countries AMC engagement group	For AMC92 countries to feel engaged and represented in key processes and influence evaluation findings. Also to influence COVAX Facility/AMC and country communications	Needs to clearly present the findings most relevant to LMIC governments, demonstrating an awareness of their role, concerns and voice in the evaluation process and COVAX	Actively engage	Regular - throughout MSE	Engagement in evaluation activity, recommendations on co-creation, learning points, sense-making workshops as relevant Evaluation reports Synthesis products	AMC Engagement Group meetings COVAX LMIC implementing countries contact lists	Evaluation entities drawing on inputs from relevant stakeholder groups	ELU / country communications team	Phase 1, 2022-2023: Immediate course correction findings of formative review and baseline to be available ahead of Oct PPC and Nov Board meetings in 2022 Likely rapid review to focus on country readiness during 2022-2023

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To understand how AMC donors and SFPs should continue to engage with the COVAX Facility and inform decisions regarding their role in course corrections and future pandemics	4 3 2 1	Governments – mostly focused on high- and higher-middle income countries COVAX Shareholders Council	For SFPs to feel able to make informed decisions supported by the evaluation findings	Needs to clearly and concisely present the strengths and limitations of the COVAX Facility and AMC, it's results and give priority to the relevant recommendations	Ensure aligned	At key evaluation points - to share findings and learning from summative evaluations and rapid reviews where content is relevant	Engagement in evaluation activity, recommendations on co-creation, learning points, sense-making workshops as relevant Evaluation reports Synthesis products	COVAX Shareholders Committee meetings COVAX SFP and donor countries contact lists	Evaluation entities drawing on inputs from relevant stakeholder groups	ELU	Throughout all 3 phases , findings will produce evidence to inform this understanding, noting evaluation focus will need to align with any evolutions of the COVAX Facility and AMC model
To understand primarily what COVAX Facility and AMC investments are being made and how these are complementing the work of others, including through the ACT-A	4 3 2 1	Bill & Melinda Gates Foundation, FIND, the Global Fund, Unitaaid, Wellcome, and the World Bank	To feel able to make informed decisions about how they engage and support the COVAX Facility and AMC, supported by the evaluation findings	Needs to clearly and concisely present the strength and limitations of the COVAX Facility and AMC, it's results and give priority to the relevant recommendations	Ensure aligned	At key evaluation points - to share findings and learning from summative evaluations and rapid reviews where content is relevant	Engagement in evaluation activity Evaluation reports Synthesis products	TRG, RAG, Market-Sensitive Decisions Committee (MSDC), Audit and Finance Committee (AFC), ACT-A	Evaluation entities drawing on inputs from relevant stakeholder groups	ELU	Phase 1, 2022-2023: findings of formative review and baseline to be available ahead of Oct PPC and Nov Board meetings in 2022 Exploration of this topic will also likely continue through Phases 2 and 3
To understand the scope and success of actions to engage with vaccine manufacturers to develop a broad portfolio of affordable vaccines, increase supply and secure this supply for COVAX participating countries, and whether other strategies may have merit (e.g. IP waivers, technology transfer) To learn lessons from manufacturers further along the vaccine production and supply process, and/or those operating in similar/comparable contexts	4 2 3 1	Vaccine industry	To gain a stronger understanding of how COVAX intends to engage with vaccine manufacturers, and implications for engagement and supply mechanisms	Clear and concise messaging around COVAX Facility and AMC plans for engagement/support to manufacturers.	Keep informed	At key evaluation points - to share findings and learning from summative evaluations and rapid reviews where content is relevant.	Engagement in evaluation activity Evaluation reports Synthesis products	Research and Development and Manufacturing Investment Committee (RDMIC)	Evaluation entities drawing on inputs from relevant stakeholder groups.	ELU	Phase 1, 2022-2023: findings of formative review and baseline to be available ahead of Oct PPC and Nov Board meetings in 2022 Lesson learning from comparator studies will be carried out at different points through Phases 1, 2 and 3

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To understand high level implications for sourcing and deploying vaccines in pandemic context	4 3	Research and technical health institutes , including SAGE and academia	To share key learning widely for the global public good	Clear, concise messaging within a future facing frame	Keep informed	At key evaluation points - to share findings and learning from summative evaluations and rapid reviews where content is relevant	Evaluation reports Synthesis products	Research and Development and Manufacturing Investment Committee (RDMIC)	Evaluation entities drawing on inputs from relevant stakeholder groups	ELU & evaluation entities through own web and social media presence	Phases 2 (2024-2027) and 3 (2028-2030)
To understand what has been achieved within context, and how equity could have been better served. Clarity on accountability mechanism within COVAX Facility and AMC	3 4	Media and global Health community writ large	To share key learning widely for the global public good	Need to promote transparency and balance through communication. Clear headline messages	Keep informed	At key evaluation points - to share findings and learning from summative evaluations and rapid reviews where content is relevant	Evaluation reports Synthesis products	Press releases, Gavi Alliance social media channels	Gavi Alliance Communications team in collaboration with COVAX ELU	Gavi Alliance Communications team in collaboration with ELU	Throughout all 3 phases, although focus on results will be stronger in Phases 2 and 3

Annex 17: Dissemination plan

Table 25 - Dissemination plan

Date/timeline	Evaluation outputs	Communication medium	Channels	Intended audience	Responsibility for dissemination
Q3 2022: Formative review and baseline study findings	Formative review and baseline study report, including synthesis products on e.g. barriers and enablers to achieving outcomes and goals and how these relate to course correction needs within the COVAX Facility and COVAX AMC and Gavi 5.0	Interim reports, executive summary & translated into slide decks. Including use of visuals and infographics desirable to increase accessibility	PPC and Board Meetings Office of the COVAX Facility team meetings	PPC Gavi Board Office of the COVAX Facility COVAX implementing partners (CEPI, WHO, UNICEF)	Office of the COVAX ELU
TIMES TBC: Periodic evaluations	Evaluation report, including synthesis products on e.g. barriers and enablers to achieving outcomes and goals and how these relate to course correction needs within the COVAX Facility and COVAX AMC and Gavi 5.0 + Learning from comparator agencies/arrangements/contexts + Learning from country case studies (including e.g. looking at the end-to-end process for individual countries)	Interim reports, executive summary & translated into slide decks + Concise learning briefs (synthesis product) & translated into slide decks. Including use of visuals and infographics desirable to increase accessibility + Varied social media platforms used by the Alliance to repurpose content and reinforce access to key messages + Q&A learning sessions online to socialise findings in key/critical areas for targeted groups	PPC and Board Meetings Office of the COVAX Facility team meetings	PPC Gavi Board Office of the COVAX Facility COVAX implementing partners (CEPI, WHO, UNICEF) Governments – implementers (LIC, LMIC, UMIC, HIC) Governments – donors (Germany, Japan, USA, etc.) CSOs – implementers Multilaterals Research and technical health institutes and academia Media	Office of the COVAX ELU
TIMES TBC: Ad hoc rapid reviews	Content TBC as needs arise – e.g. learning briefs on allocation, humanitarian buffer, procurement, support to country readiness, etc.	Concise briefs & translated into slide decks for internal use. Including use of visuals and infographics desirable to increase accessibility + Varied social media platforms used by the Alliance to repurpose content and reinforce access to key messages targeting external audiences + Q&A learning webinars to socialise findings in key/critical areas for targeted groups	PPC and Board Meetings Office of the COVAX Facility team meeting	TBC depending on focus of study. E.g. if exploring engagement with manufacturers will be important to ensure messages are targeted/accessible to that group E.g. Vaccine industry E.g. CSOs (where learning relates specifically to their engagement) E.g. multilaterals (where learning relates to how they can align and engage)	Office of the COVAX ELU

Annex 18: Line of sight from EA to evaluation design

Table 26 - Line of sight from EA to evaluation design

Observation from evaluability assessment	Implication for evaluation design
Right things – design	
<p><i>Overall</i>, the COVAX Facility and COVAX AMC design is complicated but coherent. Across the many different project components, COVAX implementing partners work in interconnected ways to fulfill roles and responsibilities that facilitate COVAX Facility and COVAX AMC results. COVAX also operates in a highly complex operating environment.</p>	<p>The evaluation is focused on Gavi and the COVAX Facility and COVAX AMC, although it is unlikely to be possible or helpful to evaluate these in isolation. Rather, the evaluation will consider the interconnectedness of roles, responsibilities and ways of working between agencies to facilitate COVAX Facility and COVAX AMC results. The evaluation will consider the COVAX Facility and COVAX AMC in the context of COVAX and ACT-A more generally and of the geopolitical and wider contextual factors at play. This will involve taking into consideration factors both within and outside of Gavi's direct control, and factors over which it has both higher and lower levels of control and for which it can be held accountable.</p>
<p>The EA did not include the planned participatory exercise with wider Office of the COVAX Facility staff to systematically explore the ToC, document assumptions and build consensus around it.</p>	<p>A ToC development workshop is proposed at the outset of the formative review and baseline study to ensure that the ToC is sufficiently well developed to be evaluable. This will elaborate on the causal pathways and comprehensively include assumptions – explicit, implicit, documented and undocumented. It will also capture all previous and future design iterations.</p>
<p><i>Specific components</i> of the ToC are not clear and/or coherent. For instance, the COVAX vision of 'end the acute phase of the pandemic by the end of 2021' was never clearly defined nor plausible.</p>	<p>The ToC development workshop will seek to clarify issues such as this. Where this is not possible, these will be presented as findings and act as the basis for recommendations for revision.</p>
<p>It is difficult to define and operationalize a counterfactual for the COVAX Facility and COVAX AMC, due to its unique character as the first and only global procurement and delivery mechanism.</p>	<p>Analysis is based on a narrower counterfactual wherein we consider how different design options across specific programmatic components would have played out. One such alternative design choice counterfactual may be to understand if/how technology transfer could have been prioritized and included within the intervention design. Comparators are also used to supplement the analysis.</p>
<p>Particular areas of stakeholder interest in the COVAX Facility and COVAX AMC design include:</p> <ul style="list-style-type: none"> ▪ The design choice to be a global purchasing and allocation mechanism (i.e. for all countries). ▪ The appropriateness of specific market shaping strategies, combining push and pull mechanisms. ▪ The appropriateness and feasibility of the allocation mechanism design, based on principles of equity and fairness. ▪ The relative balance between efforts focused on scaling vaccine procurement and scaling country-level delivery. 	<p>These questions are included as key issues to explore within the formative review and baseline study, with some also presented as examples of rapid reviews.</p>
Right way – implementation	
<p>Data limitations mean that:</p> <ul style="list-style-type: none"> ▪ Despite a wealth of information on implementation progress/decision points, data points are not always aligned with each other, and it is likely that some will be contested. ▪ There is a need to interpret implementation progress in the context of the COVAX Facility and COVAX AMC being set up as an emergency response to a public health emergency and highly uncertain operating environment. 	<p>The evaluation design places substantial emphasis on conducting a history of decisions and timeline analysis to provide a comprehensive overview of implementation decisions to date and the specific context in which these decisions were made and the operational structures and processes were implemented. Through a range of methods specific to the needs of each EQ, benchmarking against objective criteria and comparator analysis are then used to determine, in the prevailing context, what 'good' looked like and to provide the basis (alongside comparator analysis) against which to assess the appropriateness of decision making. This includes a capability, culture and practice mapping and assessment, risk management analysis, costing assessment and analysis of stakeholder engagement.</p>
<p>The wording of some sub-EQs was vague and could lead to misunderstanding/different expectations on the scope of work.</p> <p>The EA also highlighted that the EQs do not specifically cover all of the programmatic areas of the COVAX Facility and COVAX AMC ToC, such as market shaping, procurement and delivery, equitable allocation and CRD. As</p>	<p>Suggested amendments have been made to a series of EQs to provide greater clarity and focus to the questions.</p> <p>A set of EQs is included in the revised set of EQs for the evaluation design in order to understand implementation of specific programmatic implementation components (resource mobilization, market shaping, procurement and delivery, equitable allocation and CRD).</p>

such, there is some scope for differing expectations on the scope of work.	
Particular areas of stakeholder interest for the evaluation to explore include: 1. The processes in place to communicate and engage with stakeholders. 2. Whether internal systems and processes are appropriate to working in an emergency setting, given that they utilize Gavi capacity. 3. Clarity of roles and responsibilities and the appropriateness of governance structures to guide decision making and ensure accountability. 4. The importance of transparency in dealings between vaccine manufacturers, COVAX and participating countries, who have also engaged in bilateral procurement, to achieving COVAX Facility and COVAX AMC goals and objectives.	Dealing with each point in turn: 1. Communications processes have been included within EQ 2.1.4. 2. All EQs under the operational domain consider whether internal systems and processes are fit for purpose given the context of working in a public health emergency. 3. EQ 2.1.1 is focused on understanding whether management structures and governance arrangements been fit for purpose and will include capability, culture and practice mapping and assessment, and RACI analysis. 4. Transparency is considered as an important principle across the evaluation design, including as a criterion to assess equity in the design process, and with the following stage-specific questions posed within the formative review and baseline study: <i>'How well have communications functioned to enable transparency in COVAX Facility and COVAX AMC operations and dealings, and to facilitate joint efforts to achieve common outcomes?'</i>
Right results	
There are gaps in the availability of outcome data on the recipients of COVID-19 vaccines – specifically, whether vaccines are being administered to intended vulnerable populations in participant countries, and with some impact metrics still being finalized.	It is anticipated that quantitative analysis for some results will rely on estimates and/or the collation of country data outside of official COVAX reporting channels, which may be challenging to collect. Recommendations are also made to Gavi to: 1. Seek ways to collect robust data on the recipients of COVID-19 vaccines, including disaggregation by vulnerable populations in participant countries. 2. Finalize impact metrics on reducing morbidity, mortality and the socioeconomic impact of the pandemic.
Assessing the contribution of the COVAX Facility and COVAX AMC to observed outcomes will require significant data collection and analysis. The assessment is complicated by the complexity of the evaluand – notably with many different project components and multiple interactions of different stakeholders, which makes the attribution of causes to identified effects challenging – and the timing of the intervention and the extent to which achievement of overall impacts and goals is realistically expected during the evaluation period. As such, an evaluation approach that can provide rigorous assessment of causality over time and which is based on a thorough understanding of the context and operating environment is recommended.	It is recommended that the evaluation design be based around a generative causation, theory-based approach, which will provide the most complete approach to causal explanation. Contribution analysis will meet this need but the emphasis should be placed on understanding the importance of context to the achievement of results and on ensuring external validity.
There is significant interest in an assessment of the results of the COVAX Facility and COVAX AMC against the benchmark of fair and equitable access to COVID-19 vaccines, and the reasons why intended results were or were not achieved.	Framing the overall MSE within a theory-based approach will support cross-EQ synthesis and enable the formulation of strong responses to high-level EQs, overall conclusions and recommendations on design, implementation and results.
Learning	
Barriers to effective implementation have been documented, but there is a gap in the evidence on how implementation in some areas (resource mobilization, market shaping, procurement and delivery, equitable allocation and CRD) influences the achievement of results.	EQ 4.2 has been retained in the evaluation scope of work but situated within Module 3 on right results to ensure that data collection and analysis in this area is prioritized.
Another gap relates to lessons learned from participating countries on which population groups are receiving vaccines, and how/whether equitable distribution is being achieved. This has implications for the Gavi 5.0 learning priority in terms of understanding how to reach zero-dose communities.	The evaluation will draw on a rich pool of qualitative learning, available through: • WHO regional teams, who host regular webinars to engage with countries through Q&A. • The BID Initiative ¹¹² library (a learning network between countries and between regional and global partners) and additional learning networks. ¹¹³ • Gavi country programs and communication staff regular engagements with country implementers.
A significant amount of rapid, day-to-day learning takes place but is not necessarily documented or shared with the ELU team in a systematic way.	The evaluation will respond to this gap: (a) through stocktake and reflection; and (b) by ensuring that synthesis products respond to specific learning needs identified in collaboration with the ELU. It is also explicitly designed to prioritize harmonization between evaluation products and the ELU's continuous learning function.

¹¹² BID Initiative. *Resource Library*. <https://bidinitiative.org/resource-library/>

¹¹³ E.g. Geneva Learning Foundation, TechNet, etc.

<p>There is scope to use comparator analysis to learn from other agencies, arrangements and contexts.</p>	<p>Comparator analysis is proposed as a method for Modules 1 and 2, and learning from these analyses will be synthesized for EQ 4.4. An additional EQ has also been included to learn from experiences across country contexts: <i>What can be learned from a comparison of countries' experiences of securing maximum possible vaccination supply and coverage, and applied to the COVAX Facility and/or AMC for the achievement of intended outcomes and impact?</i></p>
<p>There is a clear demand and need for learning to meet the evaluation purpose and stakeholder needs. The main challenge related to usefulness is the dynamic context resulting in quickly changing learning needs and priorities, which presents challenges for ensuring evaluation work is timely enough to meet those needs.</p>	<p>In such a dynamic context this will require commitment from the ELU and Office of the COVAX Facility to a formative evaluation approach and making good use of anticipated 'learning points' and other meetings. The evaluation approach also seeks to blend the principles of both (i) a periodic and phased formative-summative evaluation and (ii) real-time evaluation. The latter is designed to enable the evaluation of specific components of the COVAX Facility and COVAX AMC ToC in real time to meet quickly changing needs.</p>
<p>Evaluation question 4.1 – on the strength of Gavi/COVAX Facility and COVAX AMC systems and processes to capture, collate and disseminate learning – is not considered as high a priority as others.</p>	<p>The question has been excluded from the scope of work.</p>
Cross-cutting	
<p>There is a strong need and stakeholder demand (particularly from the Office of the COVAX Facility and other implementing partners – i.e. CEPI, UNICEF and WHO) for an evaluation function that uses evidence and supports rapid learning to support future design iterations. There is also a need, stemming from the Gavi Board requirement but also from the expressed desire from stakeholders external to COVAX, for a fully independent and robust evaluation that meets an accountability objective.</p>	<p>To meet stakeholder needs, the evaluation approach blends the principles of both (i) a periodic and phased formative-summative evaluation and (ii) real-time evaluation. This is designed to enable the evaluation of specific components of the COVAX Facility and COVAX AMC ToC in real time, as well as provide a coherent evaluation narrative on its overall contribution to outcomes and impact.</p>
<p>The nature of the evaluand, the context it is operating in and the need to take into consideration factors both within and outside of Gavi's direct control, and factors over which it has both higher and lower levels of control and can be held accountable for, require a complexity-aware design and dictates that some approaches will be more relevant and feasible to application than others. Moreover, the type of questions being asked of the evaluation are a mix of 'how well', 'how much' and 'how' questions.</p>	<p>The types of EQs, the demand for findings at different times for different uses, and the scale of the evaluation mean that no single method or approach will fully address the requirements of the COVAX Facility and COVAX AMC evaluation. A phased, multi-module and mixed-method design is proposed, within an overall realist-informed approach. This recognizes the importance of studying the influence of context on causality as part of a complexity-informed evaluation approach.</p>
<p>Accessing stakeholders through KIIs and focus group discussions will be critical to generating the evidence required to answer the EQs robustly, especially those where significant analysis and triangulation are required. While country stakeholders and the staff of COVAX implementing partners are extremely busy and will have limited time to engage with the evaluation, the EA process did indicate strong interest and willingness to do so.</p>	<p>The evaluation design is cognizant of limited stakeholder availability to engage and builds in sufficient flexibility to secure both broad-based inputs and the inputs of key stakeholders from COVAX implementing partners and participating countries.</p>
<p>There are different stakeholder needs and expectations from the evaluation. In particular, COVAX implementing partners are most in need of – in the short term at least – rapid learning to inform course correction. As noted above, the COVAX Facility and COVAX AMC design is expected to continue evolving and there is potential for the evaluation to influence and inform design decision making. The Gavi Board requires that the evaluation be used as part of good governance to demonstrate accountability for the use of ODA and achievement of results to donors, investors and countries participating in COVAX. This is broadly aligned to a strong expectation from many other stakeholders for a holistic evaluation that seeks to understand whether COVAX has been able to overcome power imbalances to ensure equitable global access to COVID-19 vaccines and to learn lessons for future pandemic preparedness.</p>	<p>The evaluation design seeks to balance different stakeholder needs and expectations, combining the principles of both (i) a periodic and phased formative-summative evaluation and (ii) real-time evaluation (see above).</p> <p>The evaluation places emphasis on understanding how/whether equity has been prioritized in both process and outcomes, and is considered in the following ways:¹¹⁴</p> <ul style="list-style-type: none"> ▪ in the distribution of and access to vaccines across country income categories (i.e. HICs, MICs and LICs); ▪ in the distribution of and access to vaccines between individual countries; and ▪ in the distribution of and access to vaccines within countries, such as between geographical areas and population groups.

¹¹⁴ While the latter should be considered, it is beyond the COVAX Facility and COVAX AMC's sphere of responsibility and control, and may not be the focus of the evaluation.

Annex 19: Summary of evaluation design options

Section 3 and Section 0 in the report present a series of options and recommendations and, based on the recommended course of action, further options and recommendations are made. These are summarized in the table below.

Table 27 - Summary of evaluation design options

Evaluation design option	Recommended course of action
Strategic and/or methodological considerations	
<p>The following are priority users and uses of the evaluation:</p> <ul style="list-style-type: none"> ▪ Gavi Board, primarily to hold the Secretariat and Office of the COVAX Facility for their role in implementing the COVAX Facility and AMC, alongside other implementing partners, for the use of ODA and achievement of results to donors, investors and all countries participating in COVAX. ▪ COVAX implementing partners, particularly the Gavi Secretariat and Office of the COVAX Facility to enable (a) rigorous testing, learning and adjustment of the complex COVAX Facility and COVAX AMC model to ensure fitness for purpose within its operating environment and optimize the conditions for desired results to be achieved; and (b) comprehensive tracking of the progress and contribution of the COVAX Facility and COVAX AMC to intended results, with explanations of how and why this is or is not being achieved. ▪ The global health community writ large, including AMC countries, with a proactive focus on equity, to report objectively on the extent to which COVAX has been able to address power imbalances to ensure equitable access to COVID-19 vaccines and inform future pandemic preparedness. 	<ul style="list-style-type: none"> ▪ It is implicitly recommended that the evaluation design seek to meet all three uses as robustly and practically as possible, without any bias or preference between them. ▪ Equity should be both prioritized as a central principle in the design of the COVAX Facility and AMC (equity in process) and reflected in the results achieved (equity in outcomes). Equity should be considered in at least three ways: <ul style="list-style-type: none"> ○ in the distribution of and access to vaccines across country income categories (i.e. HICs, MICs and LICs); ○ in the distribution of and access to vaccines between individual countries; and ○ in the distribution of and access to vaccines within countries, such as between geographical areas and population groups.
<p>In terms of the scope of work, the evaluation is focused on Gavi and the COVAX Facility and AMC, although it is unlikely to be possible or most helpful to evaluate these in isolation.</p>	<p>The evaluation should consider:</p> <ul style="list-style-type: none"> ▪ The interconnectedness of roles, responsibilities and ways of working between agencies to facilitate COVAX Facility and COVAX AMC results. ▪ The COVAX Facility and COVAX AMC in the context of COVAX and ACT-A more generally and of the geopolitical and wider contextual factors at play. This will necessarily involve taking into consideration factors both within and outside of Gavi's direct control and factors over which it has both higher and lower levels of control and can be held accountable for.
<ul style="list-style-type: none"> ▪ The findings of the EA indicate a strong need and stakeholder demand for an evaluation function that uses evidence and supports rapid learning to support future design iterations. A 'real-time evaluation' approach would be suitable to meet this need. ▪ The EQs, however, stemming from the Gavi Board requirement (but also from the expressed desire from stakeholders external to COVAX) for a fully independent and robust evaluation that 	<p>To meet the priority users and uses for the evaluation and all stakeholder needs, the evaluation approach should blend the principles of both (i) a periodic and phased formative-summative evaluation, and (ii) real-time evaluation.</p> <p>The nature of the evaluation and the context it is operating in, as well as the need to take into consideration factors both within and outside of Gavi's direct control and factors over which it has both</p>

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<p>meets an accountability objective, would require a more holistic evaluation of what has worked well and less well in the design, set-up and implementation of the COVAX Facility and AMC, and in terms of what has been delivered and what results have been achieved. A periodic and phased formative-summative²⁵evaluation approach – i.e. conducted at predetermined time intervals, where the scope shifts from design and early implementation at the outset and places more weight on assessing results over time – would typically meet this need.²⁶ Such an approach would also be appropriate for generating learning to inform course correction and future pandemic preparedness. However, such learning may not always come at the right times to inform course correction in a highly dynamic environment.</p> <ul style="list-style-type: none"> ▪ A blended approach would enable the evaluation of specific components of the COVAX Facility and AMC ToC in real time, as well as provide a coherent evaluation narrative on its overall contribution to outcomes and impact. In so doing, the approach can be learning and utilization-focused while still able to cover the entire ToC and scope of work (as required), provide full responses to the EQs, and meet the stated evaluation purpose on accountability. 	<p>higher and lower levels of control and can be held accountable for, requires a complexity-aware design and dictates that some approaches will be more relevant and feasible to application than others. Moreover, the type of questions being asked of the evaluation are a mix of ‘how well’, ‘how much’ and ‘how’ questions. The types of EQs, the demand for findings at different times for different uses, and the scale of the evaluation mean that no single method or approach will fully address the requirements of the COVAX Facility and AMC evaluation. A phased, multi-module and mixed-method design is required.</p>
<p>While a mixed-method design will be appropriate, there are benefits to adopting a consistent overarching overall approach and method, as outlined below. To meet the evaluation purpose, the evaluation will need to make causal inference – i.e. to establish whether and how implementation of the COVAX Facility and COVAX AMC has contributed to observed results. There are three types of approach for establishing cause-and-effect linkage:</p> <ul style="list-style-type: none"> ▪ Regularity and counterfactual frameworks are ruled out since data on outcomes is sparse and such approaches do not provide insights into the causal mechanism (i.e. how and why the mechanisms in question, operating in the prevailing context, generate social behavior and explain how outcomes were achieved). ▪ Configurational approaches are also ruled out since such approaches only identify the ingredients of the causal mechanism but do not provide in-depth insight of how and why outcomes were achieved. Such insight is critical to answering the EQs and understanding how and why the COVAX Facility and COVAX AMC has contributed to the achievement of intended outcomes and goals. ▪ Generative causation approaches are designed to identify the mechanisms and contexts that explain outcome patterns and so provide the most complete approach to causal explanation. This relies on generating a strong theory of how the mechanism(s) interacts in the prevailing context to achieve the intended outcomes. This requires an explicit ToC, including the mechanisms of change, assumptions, risks and context that enable or hinder the theory from working as intended. Against this theory, evaluations can examine the extent to which and how an intervention has produced or influenced observed results. 	<p>It is recommended that the evaluation design be based around a generative causation, theory-based approach. Operationalizing a theory-based approach requires a well-defined ToC that captures the mechanisms and contexts that explain how the intended outcomes will be achieved, against which the design, implementation and results can be evaluated. We recognize that the COVAX Facility and COVAX AMC design and the context in which they are operating have evolved substantially over time and are likely to continue to do so. As such, and to ensure that the evaluation findings are as current as practicable, the ToC will require frequent revision and updating throughout the evaluation process.</p> <p>Our approach to evolving the ToC thus far has involved: (a) eliciting various stakeholders’ existing conceptions of how the COVAX Facility and AMC is expected to work; and (b) constructing a single model that is evaluable but seeks to represent the diversity of stakeholder perceptions elicited. We have not yet conducted the planned participatory exercise with wider Office of the COVAX Facility staff to systematically explore and build consensus around the ToC for the evaluation. This workshop should take place at the outset of the proposed formative review and baseline study with this purpose in mind and to ensure that the ToC is sufficiently well developed to be evaluable.</p>
<p>Within the theory-based family of evaluation approaches, there is a number of potential options to evaluating the COVAX Facility and COVAX AMC, each with trade-offs in terms of their ability to meet the different evaluation purposes (i.e. accountability, learning to inform midterm course correction, and learning to inform future pandemic preparedness) and answer the EQs.</p>	<p>Within the family of generative causation, TBE approaches, the overall MSE should utilize contribution analysis and process tracing as the primary methods. This is a practical solution to implementing a complex evaluation with limited resources and stakeholder availability.</p> <p>We note, however, the importance of understanding how the context has shaped and influenced design, implementation and results to ensure external validity – i.e. how well findings can be expected to apply</p>

<p>The influential Stern paper on options for evaluation in international development³⁴ identifies two types of approach: process-oriented and mechanism-oriented, though notes these are usually inextricably interwoven.</p> <ul style="list-style-type: none"> ▪ <i>Process-oriented:</i> Follows various causal links in a chain of implementation of an intervention, ‘built around a “theory” that is a set of assumptions about how the intervention achieves its objectives and under what conditions’.³⁵ The most commonly used are contribution analysis and process tracing. ▪ <i>Mechanism-based:</i> In order to make a causal claim, a mechanism that ‘makes things happen’ needs to be identified. But mechanisms do not operate in a vacuum – the interaction with context is important. Mechanism-based evaluation seeks the connection between causes and effects through deep theoretical analysis, based on mid-range theories.³⁶ This stems from a ‘realist’ perspective and its most common method is realist evaluation.³⁷ <p>Contribution analysis and realist evaluation are both appealing, and either could be used to good effect to answer the EQs. However, the EA findings (see Section 2.3), notably around the limited availability of stakeholders to engage with the evaluation and the ability to directly answer the EQs of interest, suggest that contribution analysis will be the most practical and useful to implement.</p>	<p>to other settings. Our approach to implementing contribution analysis is set out in Section 4.1.3.3 and Annex 12. Approaching the evaluation in this way will involve repeatedly looping back to test evidence against the ToC on how and why change happens, and as such would allow for repeated updates to the ToC to be made across the phases of the evaluation. This approach will generate learning for immediate course correction and will deal well with the dynamic nature of the evaluand design and operating environment. Gaining an in-depth understanding of how well the COVAX Facility and COVAX AMC have worked in the context of the COVID-19 pandemic response will also be useful for generating transformative learning on future pandemic responses.</p>
<p>The evaluation should support a strong continuous learning function, led by the Office of the COVAX Facility/Gavi ELU. There is a strong need for the Office of the COVAX Facility/Gavi ELU to provide such a function, including to generate, collate through the learning library, analyze and use learning for immediate course correction and future pandemic preparedness. The evaluation can support this function – through the synthesis of learning across all evaluation activity and through development of synthesis learning products – to facilitate uptake of lessons learned among key stakeholder groups. We identify three potential options providing different levels of support to the learning function administered by the Office of the COVAX Facility/Gavi ELU:</p> <ul style="list-style-type: none"> ▪ Light-touch learning support: This is our recommended option. This option relies on the Office of the COVAX Facility/Gavi ELU leading on activity related to learning uptake of evaluation findings. This option affords the external evaluation team maximum independence, which is important to stakeholder groups as we discovered through document review and KIIs. ▪ Mid-level learning support: This would provide a discrete amount of additional technical support to the learning function to support action/uptake of learning arising from evaluations and rapid reviews. While this option could help MEL and wider Office of the COVAX Facility staff to operationalize recommendations, it could reduce the perception of evaluation team independence. ▪ Semi-embedded learning support: This would provide additional technical support to foster explicit linkage between the COVAX Facility and AMC MSE activity and the wider Gavi 5.0 Learning System learning hubs. This could help to promote cross-pollination of learning arising from formative review and baseline country work and potential for triangulation of learning from hubs related to country experiences. However, this option implies an even more reduced level of independence and could raise concerns around potential conflict of interest. 	<p>A light-touch learning support option is recommended, involving support to facilitate ‘learning point’ meetings, synthesize lessons learned arising from all evaluation activities and facilitate validation of lessons learned (e.g. through sense-making workshops or recommendation co-creation workshops with relevant teams). This approach would rely on the Office of the COVAX Facility/Gavi ELU to facilitate learning action sessions (i.e. to clarify implications of the recommendations, what needs to happen, by who and by when, etc.), and generally support the use of learning for decision making and course correction. This would ensure that the evaluation team helpfully supports the learning function but retains independence from the evaluand in terms of how learning is used.</p> <p>For the avoidance of doubt, while the co-creation processes should help to build consensus on conclusions and recommendations, these should remain the responsibility of the independent evaluators, who must be free to reject suggestions of others if it is felt appropriate to do so.</p>

<p>Types and phasing of evaluation activity: We distinguish between (i) baseline, midterm and end-term formative-summative evaluations covering the full scope of work that meets an accountability objective, and (ii) ‘rapid reviews’ focused on specific parts of the ToC where learning is required (e.g. to address operational issues and influence rapid course correction).</p> <p>Types of EQs: We also distinguish between three types of questions for evaluative purposes:</p> <ul style="list-style-type: none"> ▪ The core EQs are framed at a relatively high level and are designed to stay fairly constant over the entire MSE (although more could be added as needed). These will be answered through the formative-summative evaluations over time. ▪ Stage-specific EQs, nested within each of the core EQs, will be framed for each formative-summative evaluation process. These EQs will ensure that the evaluation is answering the most relevant questions and is focused on those questions that are possible to answer at any given moment in time.⁴⁴ ▪ Rapid reviews will be designed to focus on particular areas of interest/need. <p>The focus and scope of stage-specific EQs and rapid reviews would be agreed with the Office of the COVAX Facility and implementing partners, who would be the primary audience. In contrast, the focus and scope of the broader formative and summative evaluations would be agreed with the Gavi Board and broader constituency groups, and would have a wider primary audience.</p>	<p>Types and phasing of evaluation activity: It is recommended that baseline, midterm and end-term formative-summative evaluations are conducted every 1–2 years, and incorporate stage-specific EQs that relate to and over time aggregate up to answer the core EQs. It is further recommended that these evaluation processes are interspersed with ‘rapid reviews’ focused on specific parts of the ToC where learning is required (e.g. to address operational issues and influence rapid course correction).</p> <p>Harmonization across MEL functions: The formative-summative evaluations, including stage-specific EQs, will need to be aligned to rapid reviews and the COVAX Facility and COVAX AMC’s continuous learning function, such that each can complement, benefit and build from the other.</p>
<p>Operational considerations</p>	
<p>Stakeholder participation in evaluation processes: All evaluation activity would be conducted in as participatory a manner as possible for all constituency groups engaged in the COVAX Facility and COVAX AMC. This will include making efforts to accommodate the limited time some stakeholders are able to devote to the evaluation, such as by: stating expectations for stakeholder engagement upfront; minimizing the number of requests made of each stakeholder, holding focus group discussions where feasible, and use of web-surveys; basing the timing of evaluation exercises in part on stakeholder availability; and allowing sufficient time to collect data in the evaluation workplan to give greater flexibility to stakeholders on when to provide their inputs.</p> <p>For KIIs, it is suggested that stakeholders are purposively sampled – as they were for the EA and evaluation design process – in discussion with the ELU, in part based on their availability to engage with the evaluation process. We present three options for stakeholder engagement through KIIs during the formative review and baseline study, alongside the likely implications to the scope, scale and/or quality of work. We will seek Gavi’s input on these options as we start Phase 1.</p>	<p>It is recommended that the highest level of stakeholder engagement (regular) through KIIs is selected such that the evaluation process can proceed in line with best practice across the full scope of work, as anticipated.</p>

Level of stakeholder engagement through KIIIs	Implications and potential mitigating actions	
<p>1. Anticipated/regular: Broad access to a variety of stakeholders across constituency groups, engaged in and/or knowledgeable about the COVAX Facility and COVAX AMC, as well as COVAX and the ACT-A more generally, at global, regional and country levels. Expected to involve discussions with 50+ stakeholders.</p>	<p>None. Evaluation process can proceed in line with best practice across the full scope of work, as planned.</p>	
<p>2. Slightly reduced: More limited access to one or only a few representatives of stakeholder or constituency groups engaged in and/or knowledgeable about the COVAX Facility and COVAX AMC. Stakeholders would still cover the key bodies and working structures identified as critical to engage with. Expected to involve discussions with around 35 stakeholders.</p>	<p>Robustness of evaluation findings may be somewhat compromised if inputs of key stakeholders cannot be fully solicited. Particular issues could be raised with Gavi as they arise to ensure that quality is sufficient. Some narrowing of the scope of work (i.e. to exclude areas where key informants are not available) may help to resolve the issue.</p>	
<p>3. Significantly reduced: Only a selection of stakeholders and constituency groups engaged in the COVAX Facility and COVAX AMC would be accessed, including some of those previously identified as critical to engage with. Expected to involve discussions with around 20 stakeholders.</p>	<p>Robustness of evaluation findings across the entire scope of work highly likely to be substantially compromised, risking the utility of the entire evaluation process. Significant narrowing of the scope of work to focus only on areas where key informants are may resolve the issue of quality, although the evaluation would unlikely be able to report against high-level EQs and develop conclusions on overall performance to generate recommendations of relevance to the Board and PPC.</p>	
<p>Managing independence: While stage-specific EQs would be answered by the evaluation team within the time frame and boundaries of a broader evaluative process, rapid reviews could be conducted flexibly at any time. Rapid reviews could be outsourced to external consultants or firms with relevant expertise (but with mechanisms in place to coordinate the two types of evaluation activity, ensuring each draws critical inputs from the other while minimizing overlap and duplication) or included within the scope of a single evaluation contract with a service provider (but with mechanisms to avoid any real or perceived conflict of interest).</p>		<p>It is recommended that the formative-summative evaluation work and rapid evaluation work be commissioned to a single service provider. While the former could be fully costed in advance, the latter could be used from a draw down contract on a time and materials basis in order to maintain flexibility in response to needs. Mechanisms should be established to avoid any real or perceived conflict of interest.</p>

Annex 20: Feedback summary

More than 170 comments and points of feedback have been provided on draft versions of this report by the Gavi ELU, Secretariat and Office of the COVAX Facility, and a broad range of other stakeholders engaged in the operationalization of COVAX, as well as a broader set of stakeholders with an interest in COVAX. A summary of this feedback and the team's response is presented below.

How will we ensure that the evaluation has an appropriate balance of stakeholder inputs?

Feedback reaffirmed the importance of balanced and representative stakeholder input throughout the evaluation process, emphasizing the value of consultation and participation from a broad range of stakeholders in order to answer the EQs. The evaluation sets out an expectation for broad access to a variety of stakeholders across constituency groups, engaged in and/or knowledgeable about the COVAX Facility and COVAX AMC, as well as COVAX and the ACT-A more generally, at global, regional and country levels. Of particular importance is the need to engage with a broad range of representatives from the Global South, specifically AMC92 country representatives and civil society representatives, as well as key partners (e.g. AVAT, PAHO, UNICEF and WHO). It is anticipated that the formative review and baseline study involve discussions with 50+ stakeholders. The risks associated with limited stakeholder access have been outlined in the main report (Section 3.5).

How will we ensure that the evaluation captures the importance of the political environment?

Feedback was provided on the importance of context for the evaluation, particularly to recognize the potential impact of the geopolitical context on decision making for the COVAX Facility and COVAX AMC. The proposed approach places a strong weight on understanding how the COVAX Facility and COVAX AMC has worked within the geopolitics and context of the pandemic response to achieve its overall goals of strengthened equity and fairness. This will include the use of political economy analysis and benchmarking of design decisions against criteria to analyze and assess the appropriateness of the COVAX Facility and AMC design within this context. We believe this approach will sufficiently draw attention to the issues at hand and generate transformational learning for future pandemic preparedness.

How will we ensure the evaluation adequately deals with the complex evaluand and rapidly evolving dynamic context?

In addition to the importance of recognizing the impacts of the political environment, feedback emphasized the need for the evaluation to recognize and responded to the dynamic context of the COVAX Facility and COVAX AMC, as well as the pandemic more broadly. We have also proposed an approach and methods that are well suited to understanding the importance of context on implementation and results (see Section 3.3.2 and Annex 7). The approach also includes intent to frequently revisit the ToC, both to ensure it is up to date and to test how it is working through periodic evaluation processes with stage-specific questions at each juncture, interspersed with rapid reviews on specific issues of interest.

How will we ensure that the evaluation generates transformative learning?

In order for the evaluation to have value to the full range of users, feedback highlighted the importance of an approach that can enable transformative learning. We have proposed an approach that seeks to generate a change in behavior that leads to the use of learning and/or how the evaluation will answer some of the high-level strategic questions of relevance to future pandemic preparedness. The following aspects of the proposed approach look to support this process:

- **Primary learning content focus:** We have set out the intention to focus learning from the formative review and baseline study on informing course correction for the COVAX Facility and COVAX AMC and Gavi 5.0. . This is because it is the right time for this sort of learning and it will be of value now.

Later evaluation processes will have a stronger emphasis on learning for future pandemic preparedness and response.

- **Evaluation approach and methodology:** The evaluation approach places a strong emphasis on understanding the context and how this has influenced design, implementation and results. This includes PEA and game theory to explore how power imbalances and political and economic concerns and incentives have influenced the design and implementation of the COVAX Facility and COVAX AMC, and also how these incentives have influenced SFP and AMC country decisions on whether and how to engage with COVAX. This analysis of context will provide a strong basis from which to challenge the status quo.
- **Data collection:** We have proposed a robust stakeholder engagement approach and data collection process to ensure that different world views are captured. This includes interviewing global experts, both within and outside of the COVAX architecture.
- **Evaluation team:** Our team includes a Technical Advisory Group of globally recognized experts that will advise the team throughout the evaluation. It will also include a well respected and competent partner organization from the Global South to implement the evaluation, ensuring that different world views are captured.
- **Stakeholder engagement:** Our approach includes a reflective and open validation processes (e.g. sense-making/learning and validation workshops with relevant stakeholder groups) to ensure that different world views are integrated within the development and finalization of recommendations.

How are users defined?

Feedback identified the need for clarity regarding the users of the evaluation and how they are defined. The following are priority users and uses of the evaluation:

- **Gavi Board** on behalf of donors, investors, participating countries and others to provide strategic direction and hold the Gavi Secretariat to account for the use of ODA and achievement of results;
- **Office of the COVAX Facility** to enable testing, learning and adjustment of the model, progress tracking towards results, with explanations of how and why this is or is not achieved;
- The **global health community writ large**, including AMC countries, with a proactive focus on equity, to report objectively on the extent to which COVAX has been able to address power imbalances to ensure equitable access to COVID-19 vaccines, and to inform future pandemic preparedness efforts.

Annex 21: COVAX Facility & COVAX AMC Formative Review and Baseline Study – High-level overview of technical approach

In line with the findings and conclusions of the Evaluability and Evaluation Design Study, the COVAX Facility and AMC Formative Review and Baseline Study will be conducted from 2022 through 2023 and constitute ‘Phase 1’ of the multi-stage evaluation. It will include three main activities: (1) an in-depth formative review and baseline study; (2) rapid reviews in particular areas of interest/need; and (3) support for a continuous, real-time learning function.

Purpose and scope of the Formative Review and Baseline Study

The purpose of the Formative Review and Baseline Study is to:

- Inform potential course correction through early assessment of core design elements, considering both accountability for immediate results and learning for potential course correction, and
- Enable appropriate measurement over time of the effectiveness and performance of the COVAX Facility and COVAX AMC.

Given that COVAX was established in mid-2020 and the ‘baseline’ study will be conducted in 2022, the formative review and baseline study phase will review what has worked well and less well to date in the design, implementation, and results of the COVAX Facility and COVAX AMC. It offers an opportunity to test the early stages of the Theory of Change (ToC) and take a snapshot of progress against critical areas of the ToC at this point in time.

The scope of work is broken down into both *operational* aspects (management and governance, risk management, and stakeholder engagement and communications) and *programmatic* aspects (i.e. resource mobilization, market shaping, procurement and delivery, equitable allocation; and country delivery readiness).

Given the interconnectedness of roles across the COVAX pillar, the formative review and baseline study will consider responsibilities and ways of working between implementing partners to facilitate COVAX Facility and COVAX AMC results in two ways:

- It will not evaluate other COVAX implementing partners directly but will draw on the findings, conclusions and recommendations of other evaluation processes and evidence on the design, implementation and results of their work. This will aid understanding of how the ToC has played out in practice.
- It will consider the ‘contribution’ of Gavi to areas that multiple COVAX partners jointly administer, particularly those areas that Gavi is not primarily responsible for (e.g. allocation, country readiness support, procurement and delivery).

While not in scope directly, the formative review and baseline study will also consider – through an assessment of secondary data – the COVAX Facility and COVAX AMC in the context of COVAX and ACT-A more generally, and the geopolitical and wider contextual factors at play. This initial understanding will be deepened at subsequent evaluation stages. The evaluation will take into consideration factors both within and outside of Gavi’s direct control, and factors over which Gavi has both higher and lower levels of control, and for which it can be held accountable.

Methodology

The formative review and baseline study will use mixed methods and adopt a generative causation approach to generate a strong theory of how mechanism(s) interact in the prevailing context to achieve the intended outcomes, primarily using contribution analysis and process tracing to implement and directly answer the evaluation questions (EQs).

It will be articulated around four evaluation modules offering a structured hybrid design, where different methods can be employed for each module according to where they are most fit for purpose. The proposed methods will be further refined following a kick-off workshop to be held in Geneva in March 2022. The four modules will be:

1. **Right things (design):** The evaluation will interrogate whether the COVAX Facility and COVAX AMC and its components were and remain relevant to the problems they were designed to address, by assessing: (1) whether the ToC/ intervention design (and revisions) are appropriate and based on evidence and with clear assumptions; (2) what change in the pandemic or geopolitical context prompted design revisions; (3) whether and how stakeholders were involved in original design and subsequent revisions; (4) whether any design changes are needed for course correction; and (5) whether lessons can be learned for future pandemic responses. This module will include constructing a revised 'evaluation' ToC for the COVAX Facility and AMC, undertaking a political economy analysis and benchmarking of design decisions.
2. **Right ways (implementation):** A formative, learning-focused assessment of implementation progress for each of the operational and programmatic areas of the ToC:
 - a. *Operational domain:* These EQs interrogate whether the COVAX Facility and COVAX AMC have been implemented successfully, by conducting an overall assessment of the extent to which the programme has been implemented according to plans, with a specific focus on the extent to which (1) the COVAX Facility and COVAX AMC management structures and governance arrangements are fit for purpose; (2) risk management processes have been fit for purpose; (3) the costs of setting up the COVAX Facility and COVAX AMC were reasonable and appropriate; and (4) stakeholder engagement and communication has been appropriate.
 - b. *Programmatic domain:* This is focused on understanding if resource mobilization, market shaping, procurement and delivery, equitable allocation and CRD inputs, activities and outputs have been implemented successfully and as intended.

This module will include benchmarking against objective criteria and comparator analysis, process tracing and root cause analysis.

3. **Right results:** The evaluation will seek to understand the available evidence on the achievement of outcomes and goals (intended and unintended), the contribution of the COVAX Facility and COVAX AMC to these results, and the barriers and enablers to their achievement. This module will include verifying and use of COVAX Reporting Framework indicators and triangulation with other data to do a cross-country comparative portfolio analysis, and contribution analysis.
4. **Learning:** Summarizing and prioritizing lessons learned, building on the work done under the earlier modules (to inform immediate course correction) and on what can be learned from other agencies, arrangements and contexts and applied for the achievement of intended outcomes and impact. This will include opportunities for transformative learning, for instance on the overall design of the COVAX Facility and COVAX AMC and the contextual constraints which influence this design, as well as implications for future pandemic preparedness.

Three rapid reviews will also be conducted as complementary to the above four modules to generate learning required primarily by the Office of the COVAX Facility to influence course correction; generate a better understanding of the implementation context; and/or evaluate specific programmatic areas in greater detail. The topics will be further discussed and agreed upon in the early stages of the formative and baseline review phase, but they will likely relate to the broader programmatic areas of securing supply and country readiness and delivery. These are both areas where limited work has been conducted in 2020 and 2021 but are very much live discussions for programming in 2022, and where evidence generated from a rapid review would likely be useful to guide ongoing design discussions.

Data collection

Data collection will involve a broad review of the available documentation and literature, as well as a series of key informant interviews and focus group discussions across diverse stakeholders. It will also involve a series of country case studies, where country experiences can be explored in depth.

All evaluation activity will be conducted in as participatory a manner as possible, and the evaluation will engage with a broad set of stakeholder groups/ constituencies representing the key bodies and working structures involved in the governance, management and implementation of the COVAX Facility and COVAX AMC.

Risk management

Several risks have been identified for this Phase of the evaluation. These included, but are not limited to, those highlighted below, along with proposed solutions and mitigation measure.

- **The evolving nature of the pandemic and the intervention logic for the COVAX Facility and COVAX AMC may limit the applicability of EQs, findings, conclusions and recommendations.**
 - Recognizing the responsiveness of the COVAX Facility and COVAX AMC design to an evolving context, each stage of the evaluation will start with an update on design and strategy revisions since the last assessment. Every stage of the evaluation will include a ToC situation assessment and assess the relevance, coherence and appropriateness of design choices, including the decision-making process as well as the content of any design revisions. The ToC will be updated as needed.
 - This may not cover all eventualities (e.g. where COVAX was ceased midterm or where the design changed so much that prior evaluation efforts became redundant). In such a situation, the evaluation scope of work and design would need to be immediately revised.
 - Our proposed approach and methods focus on understanding the importance of context to implementation and results. This will ensure the evaluation is asking relevant questions and taking account of the evolving context. We also note that while the evaluand design has been highly dynamic in its first two years of operations, we could reasonably expect it to reach more of a steady state in years to come.
- **Fatigue within the Office of the COVAX Facility and other COVAX implementing partners, and limited bandwidth to engage with the evaluation, may reduce our ability to obtain all of the most relevant data sources and solicit sufficient evidence to robustly answer EQs. A number of steps are included within the proposed approach to mitigate this risk:**
 - The evaluation design is based around an approach that is robust but practical to implement with methods selected, in part, based on the availability of stakeholders to engage in the evaluation process. The expectations for stakeholder engagement are clearly presented in our proposed evaluation design as well as the implications of this level of engagement not being met.
 - Efforts will be made to reduce the evaluation footprint, such as by minimizing the number of requests of each stakeholder, holding focus group discussions, using web-surveys, etc. Agreement on the timing of each evaluation exercise will be based, in part, on stakeholder availability.
 - Sufficient time to collect data is built into the workplan for each evaluation exercise to give flexibility to stakeholders on when to provide their inputs.
 - Support from the Gavi EvLU will be solicited to support implementation of these steps and stimulate interest and engagement of stakeholders in the evaluation.

- **Some aspects of the evaluation may be highly sensitive and contentious, for instance in relation to the proposed PEA to understand the incentives, relationships, and distribution and contestation of power between the different stakeholders engaged in the design and operationalization of the COVAX Facility and COVAX AMC. This may result in some stakeholders seeking to discredit the evaluation findings in order to avoid addressing the issue(s).**
 - We recognize the timeliness of this independent evaluation and the high stakes involved, and have set out an approach to deliver robust, evidence-based insights in response to the EQs and to meet the evaluation purpose. Conducting evaluative work can involve delivering difficult messages on things that may not be working as well as they should, or that could be done differently. We are mindful of the intensity and level of effort the COVAX implementing partners have invested in establishing the COVAX Facility and COVAX AMC and delivering results.
 - Our communication will be clear, constructive and appreciative, but we will not shy away from being critical where this is backed by evidence. We will work hard to build relationships with key stakeholders to facilitate constructive exchanges, ensuring that what we present is always grounded in robust evidence. This will include engaging with our Technical Advisory Group to ensure messaging is tailored appropriately.

Key deliverables

The Formative Review and Baseline Study phase will begin in March 2022. It is currently expected to run to early 2023 – with an interim findings report expected to be completed by end of August 2022 and then a final report completed by end March 2023. Timing of these deliverables, and particularly the interim findings report, have been closely tied to EAC scheduled meetings as well as planned PPC and Board meetings. Additional evidence will be made available, specifically through rapid reviews, at specific intervals pending when information is needed quickly and to complement the interim and final reports.

Looking forward to subsequent phases of the multi-stage evaluation

The scope of the formative review and baseline study is on early emerging evidence against all evaluation questions included in the original Request for Proposals, but with a more in-depth focus given to modules 1 (design) and 2 (implementation), rather than module 3 (results), given the relatively early stage of the COVAX Facility and AMC operationalization. The scope of the evaluation would then shift in subsequent mid-term review(s) to place greater weight on module 3 and a summative assessment of results, while maintaining a view across the full scope of EQs. A firmer view will be sought at mid-term stage on the emerging indications of the impact of design choices and process on results achieved to date. The endline phase would then take an overall view on the impact of design choices and processes on results, and draw out a refined view of the implications of such choices.



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